



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

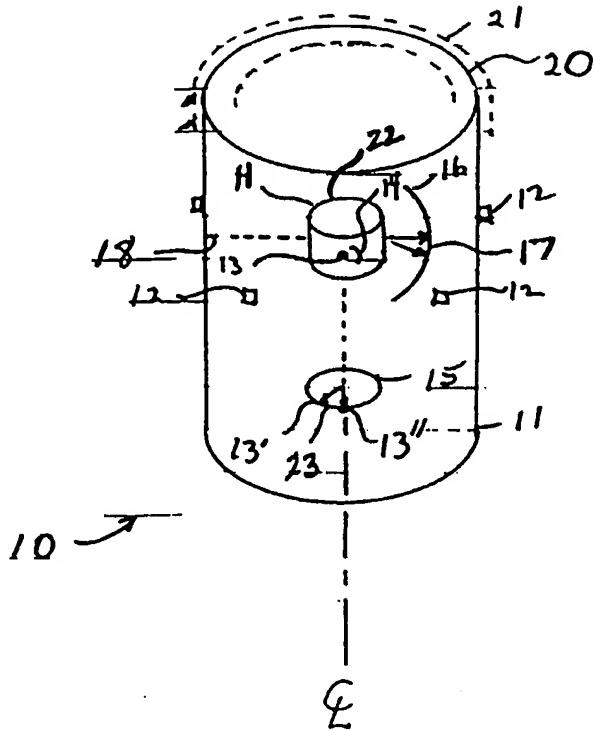
(51) International Patent Classification 6 :	A1	(11) International Publication Number: <b>WO 99/55227</b>
A61B 5/0402, 5/0404, 5/0452		(43) International Publication Date: 4 November 1999 (04.11.99)

(21) International Application Number: PCT/US99/02550	(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 5 February 1999 (05.02.99)	
(30) Priority Data: 09/067,199 27 April 1998 (27.04.98) US	
(71)(72) Applicant and Inventor: BHARAT, Patel [GB/US]; Suite 275, 17448 Highway 3, Webster, TX 77598 (US).	
(72) Inventor; and	Published
(75) Inventor/Applicant (for US only): ALHUSSINY, Karim [US/US]; Suite 275, 17448 Highway 3, Webster, TX 77598 (US).	With international search report. With amended claims.
(74) Agent: GUNN, Donald; Gunn & Associates, Suite 2900, Five Greenway Plaza, Houston, TX 77046 (US).	

## (54) Title: REMOTE CARDIAC DISORDER RESPONSE SYSTEM

## (57) Abstract

A medical facility (70) after discharge of a cardiovascular patient, can remain in contact with the patient. The patient is provided with a multiple lead EKG terminal spread (42) placed on the body. The collected EKG signals are multiplexed (46), converted into digital data (54), stabilized (56), compressed (62), then transmitted through a modulator (64) to a remote central location (70). At the central location, the transmitted EKG data is demodulated (74), decompressed (76) then analyzed using a neural network (82). It is compared with normal EKG signals, and signals captured in time from the same patient as part of the patient to get immediate treatment may be remotely activated either automatically or by an attending cardiologist. As appropriate, transmitter/receiver repeater stations (104), and synchronous satellites (110) may be used to convey these signals.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## REMOTE CARDIAC DISORDER RESPONSE SYSTEM

5

## BACKGROUND OF THE DISCLOSURE

Heart related disorders exemplified by ischemic heart disease, such as a heart attack, have been and likely will continue to be the most common cause of death in the industrialized world. An estimated 1-2 million Americans suffer from heart attack per year. Approximately half of the heart attacks are "silent" meaning they are not felt by patients. Half of the patients who sustain heart attacks die prior to arrival to hospital. The present innovation, therefore, relates to early detection and long term monitoring of heart related disorders.

There are any number of patients who are suspected of heart disease. As the effects of aging manifest in the population in general, certain heart ailments will sometimes appear suddenly, or will sometimes develop slowly over a period of time. Beginning at about age 50 for men and age 60 for women, it is usually desirable to build a data base line by conducting an annual physical which includes the collection of at least some heart data. A resting electrocardiogram (EKG) typically done with twelve leads provides modest data. It is better to obtain the test data on a stress test utilizing a treadmill. Any number of specific protocols have been developed for conducting the stress treadmill test and obtaining data from it. Technically, the heart attack is often defined as myocardial infarction (MI) and typically involves a localized shortage of oxygen or the formation of a regionalized blood clot which attributes to a shortage of oxygen in some portion of the heart. This condition is known as ischemia of the heart muscle. With age and perhaps a loss of cardiovascular strength, a patient may develop difficulties which can be observed by stethoscope, but the better approach is the collection of data with a twelve lead EKG test. The multiple lead approach simply gathers so much more data that it is much easier to measure both an initial state of affairs and to make prompt appraisal of the condition of the patient.

In any number of situations, heart patients may have a series of difficulties over time. With each small or large difficulty, there will be

some change in the base line conditions for that patient. While some measure of recovery can be had, the prevailing or normal circumstances for that patient will be, in some fashion, different than they were when that patient was just becoming an adult. So to speak, each event may 5 define or redefine the base line circumstances.

In other instances, no base line data will be available because the patient will be suddenly struck with difficulties or an ailment with results something less than fatal. Nevertheless, the ailment impacts the patient, perhaps requiring treatment for a day or two and some hospitalization. 10 Consider, for example, a middle aged person who has a modest chest pain and is immediately admitted to a hospital for observation. They may leave the hospital the next day, perhaps with medications and with warnings, perhaps dire or otherwise, demanding a change in lifestyle including a new diet, reduction of stress, and other changes in lifestyle. Instructions to 15 return to the doctor in a few days represents some sort of cold comfort which they carry with them. The return to the doctor is normally for the purpose of simply monitoring their condition. Usually, the medical personnel in charge of treatment have a fairly safe estimation of risk and health maintenance that are necessary for the patient. The patient, 20 however, is normally struck with fear and apprehension. Moreover, for many types of ailments, merely going to a doctor's office and especially going to a hospital prompts a high level of internalized stress which is manifest in the cardiovascular system. Some people become highly agitated which is reflected in an elevated pulse rate, perhaps shallow 25 breathing and other common symptoms of stress. These make the return visits to the doctor somewhat problematic. It makes it difficult at any point in time for medical intervention in that the patient is asked to calm their stress and lay aside the worries and anxieties, both real and imagined, of the next episode. They always question whether the next 30 episode will be small or large, sudden or immediate. It is fair to say that this possibly short term stress and anxiety affects the collection of the cardiovascular data, and may even mask or otherwise perturb more permanent cardiovascular indicators.

Interestingly, the collection of cardiovascular data on a long term 35 basis enables the patient to return in some fashion to a normative lifestyle. Stress and related anxiety are generally reduced. Furthermore, not

hearing the truth somehow avoids the bad news, and subject to this thinking, many patients are rebellious about return to the doctor and will not return. They reason along the lines that the knowledge will be frightening so that if they do not know, a cardiovascular abnormality will 5 somehow not harm them. The dangers in this attitude are conspicuous.

A relatively high level of anxiety is manifest by a patient who is required to undergo a stress treadmill test. Not only is there physical stress in the sense that muscles are pushed to the limit, but there is simply the anxiety that this is a test not required of healthy people. By contrast, 10 when a patient is monitored day and night, they are compelled to forget the monitoring. Monitored data will, therefore, reflect long term conditions and not be perturbed by short term, testing related emotional effects.

The monitoring of a patient around the clock, however, is clumsy because of the nature of the equipment. One common monitoring system 15 involves the Halter test. This test involves recording, in a small cassette recorder, heart data which is derived from a few EKG leads where the data are recorded on a cassette. Typically, this test is applied to a patient for only 24 hours. One aspect of the test that is burdensome is that the patient must report back to the doctor's office, return the equipment and 20 deliver the cassette. Thereafter, the cassette has to be played back on a magnetic tape deck, signals presented on a screen, and the signals inspected on the screen. In the past, this data processing has been done by hand, meaning a technician must sit and watch a replay of 24 hours of heartbeats. With a pulse of 60 beats per minute, this totals 86,400 beats 25 while it goes to 100,800 beats at 70 beats per minute. This is a fair amount of data to carefully examine. Ordinarily, that is done by hand or scanning.

Another monitoring system that has found favor is used for patients located in a hospital coronary care unit (CCU) and also to those who are 30 postoperative. Monitoring while in the CCU is self-explanatory. It provides instantaneous data to the medical staff for emergency help dependent on the telemetry signals and data from the patient. Monitoring in a postoperative mode during recovery typically involves daily or near daily attendance of the recovering patient to a hospital located exercise 35 room. It is not uncommon for patients in this status to really want to change their lifestyle. Habits die hard! After not exercising for 20 or 30

years, after eating almost anything that they desired for the same time interval, and after accumulating excess weight, the patient then gets something of a scare from the cardiovascular episode. Patients then immediately seek a new lifestyle that will fix up the accumulated problems and damages suffered in their body after 20 or 30 years of neglect. In a particular instance, they may go to an exercise facility maintained by the nearby hospital. In the exercise room, they typically will check in, be fitted with a frequency modulated (FM) telemetry system, and then will be instructed to exercise at a very gentle and slow pace on various machines under the watchful eye of medical personnel. The personnel not only watch the patient visually through a window, they also watch the FM telemetry signals received from the patient during the exercise session. Assuming that the patient is faithful to the program, they will build up some level of performance on the machines thereby strengthening their body and strengthening their heart in a post recovery mode. It is not uncommon for patients to continue this for many weeks always under the watchful eye of the attendant personnel when coupled with them via FM telemetry. However, there comes a day when the patients have to exert themselves away from the medical facility, away from the watchful eye of medical personnel who have by this time become very familiar with the patient's base line conditions and without the comfort of the telemetry system. Chores just as simple as mowing the lawn, shoveling snow from the sidewalk, or bringing in groceries can be an exertion of an unknown level, likely to cause a raised pulse, and possibly subject to stress as a result of the missing comfort provided by the FM telemetry and attendant medical personnel. That fear itself can add stress to the patient prompting even higher levels of pulse rate, shallow breathing, etc. All of these factors occur when the recovering patient forgets and undertakes a task or meets a challenge away from the safety of the controlled exercise routine. Another aspect of heart care is absence of noticeable pain. The pain in some people is minimal because there are fewer nerves in the heart region compared with the face or hands. Over time, cumulative small MI events may collectively damage the heart silently, i.e., with no alarm.

By contrast, it is most desirable that recovering patients be discharged to undertake a lifestyle which is substantially free of medical

intervention. In attempts to rebuild strength, they are encouraged to undertake walking programs and other exercise regimens which build in difficulty over time. While the difficulty may build, the patient must have the courage to jump into that program knowing that controlled physical

5 exercise is the best mode of recovery. That, however, is hard to do without medical supervision. That is difficult and a fearful thing in general terms. Monitoring of the data generated by a patient throughout the day in a post recovery mode is not possible because it would otherwise require the patient to simply live in the hospital or in the adjunct exercise facility.

10 That is unwieldy and not reasonably calculated to restore the patient to "normal" living as defined by the life of that patient. The goal, it would seem, is to restore the patient to a normal job situation with normal exercise, but to increase and enhance the exercise level so that the patient can recover to the level he or she had before the episode and also to

15 hopefully increase their strength by a new lifestyle featuring appropriate exercise. This can be seen only by observation of the patient over weeks, or preferably over many months, so that the patient can be restored to an effective status.

The present disclosure is directed to a response system for use with

20 cardiac disorder. It is intended that the term "cardiac disorder" be applied broadly. It is sufficiently broad that it would include life threatening myocardial infarction (MI below) as well as lesser circumstances which are not life threatening. It is particularly intended to respond to the above mentioned MI as well as relatively serious fibrillation situations, and lesser

25 situations such as those requiring cardioversion. It can also be used for loss of heart pace, where it picks up the slow or absent heart beat and brings an increase in rate of the heart pumping action. It is a system that is intended to be used with a mobile patient who because of underlying heart ailment, may be in a vulnerable state of health. It is also intended to

30 be used with those who have had a general loss of vitality, heart strength or have suffered significantly from aging. In all instances it is especially helpful so that patient confinement is not mandated. The patient can be permitted, with the equipment of this disclosure, to roam within radio range of a treating physician, and to always have the available assistance

35 of a treating physician.

The system contemplates telemetry from the patient to a remotely

located, central monitoring facility where records are kept. In that sense, patient mobility is considered to be ordinary, substantially unfettered roaming, and yet the patient has the luxury of knowing that untimely abnormal conditions can receive a quick response. The system is also able 5 to respond to an emergency and can even trigger a call for emergency medical rescue such as dispatching an ambulance for the patient.

Patent Application Serial No. 09/067,199 which was filed on April 27, 1998 to the United States Patent office sets forth a system which uses a set of electrodes to collect heart generated signals and transmit them to a 10 remote location. The present system further integrates with that equipment and describes a response system. The response system of this disclosure is advantageous in that medical intervention from a remote location is empowered. The patient is therefore equipped with the patient worn device set forth this disclosure. That forms a signal and hence makes 15 a transmission from the patient location to a central facility. So long as no problem arises, the centrally located equipment remains passive, i.e., it will monitor and record and yet does not need to form a response. The patient in this instance is equipped with a battery powered external monitoring system which is capable of providing monitoring of heart beat, initiating 20 defibrillation or external pace maker. Such a system is installed on the patient for varying durations as deemed necessary. In some instances, they can be installed permanently, for example at the time of cardiac surgery or along with an implanted pacemaker, but the main advantage of the present equipment is that it is portable and can monitor patients from 25 a remote site with wired or wireless communications as long as the physician deems necessary. When no longer necessary, the equipment installed on the patient and the related electrodes can be removed. This system may be very useful for a person recovering from heart surgery or a person recovering from a recent MI. In those instances, the patient is 30 troubled by apprehension and fear as they attempt to return to ordinary duties. More than just giving the patient a sense of comfort by equipping the patient with this equipment, the patient has the further sense that they are being monitored for their good health, with the possibility of intervention even should they not recognize the post recovery difficulty. 35 The electrodes applied to patient's skin, by virtue of connection via electrical wires, transmits electrical activity of the heart to the recorder

which in turn displays, records or transmits an electrical signal. This signal, for the purpose of maintaining integrity during transmission, is digitized, stored and then transmitted. It is the process of digitization of electrical signals that allows present invention detailed analysis of electrical segments of each heart beat. Such a detailed analysis of electrical activity of the heart allows this novel device to analyze electrical potentials recorded during an electrical cycle of the heart beat. Such electrical potentials, when noted in a patient especially after a heart attack, are considered harbinger of further electrical instability to come, such as fibrillation which a chaotic form of electrical rhythm. A wavelet form of analysis of the electrical activity of the heart beat, which is utilized in this device, thus allows an improved method of detecting electrical potentials.

Post recovery difficulties are almost a given for those recovering from heart attacks, open heart surgery and the like. Not every day will be as smooth as the day before. Not every day will be as free of stress, be it emotional or physical stress. Not every day will find the patient resting as much as they might need. Not every day will find the patient exercising with the appropriate routine to rebuild strength and weaned from the equipment of this disclosure.

In that gray area between full recovery on the one hand and the apprehensive, even frightened state of affairs that prevailed before that, the patient may well benefit tremendously from this type medical intervention. More importantly, this device is intended to assist early detection of heart attacks with an ability to have therapeutic intervention prior to arrival of emergency medical personnel on the scene. The medical intervention set forth in this procedure utilizes a monitoring and response system which includes a battery, a power supply and a pulse forming circuit. In addition, it connects to the patient with a set of electrodes which are mounted on the body of the patient. The electrodes are typically held on the skin of the patient in contact with the skin and are located so that they can provide a medium for recording electrical impulses as well as administering electrical shock to the surface heart region. Varying degrees of electrical shocks are necessary to either bring the heart to a regular rhythm or begin faster heart beat in case of slower heart rate. More will be noted concerning this shock later. This can be used in one of two circumstances. Where the heart loses its rhythm, the heart's electrical

activity can be restored through the pacemaker shock to restore desired heart rate. On the other hand, the heart may over speed. And here are those occasions, however, where the heart goes into unfruitful oscillations which are known as fibrillations. While the muscle of the heart will quiver, 5 no pumping benefit to the patient will occur. In that instance, a much larger jolt is administered. In effect, it is a portably delivered defibrillation shock. In the peacemaking mode, the device typically will deliver several pulses per minute, say sixty to seventy-five pulses per minute. These are relatively small pulses. In the defibrillation mode, the 10 device delivers a calculated large pulse. After an interval and in the absence of appropriate pulse restoration, another large pulse is delivered. A progression of large pulses is formed, each within a specified minimum time (e.g. five seconds) until the heart is then again significantly shocked. The defibrillation pulses grow in size while the pace making pulses remain 15 relatively smaller. Thus, in the peacemaking mode, the heart is provided with a series of relatively evenly spaced, relatively small pulses with a view of maintaining the heart at a fixed and steady rate. By contrast, in the defibrillation mode, larger pulses are delivered initially and grow larger in the event the defibrillation continues. Not much time is permitted 20 between defibrillation pulses; after the first is applied, the absence of a normal heartbeat in the next few seconds prompts the need of another defibrillation pulse, only larger. Time becomes quite urgent in that situation i.e., serious permanent harm can arise should the heart pump inadequately for any more than about two or three minutes. To that end, 25 the heart monitoring equipment switches over to the defibrillation mode and delivers all the power that is available in this life threatening situation. While there are other defibrillation and peacemaking equipment available in the market, the proposed device differs in the fact that both the monitoring of patient and the intervention of electrical shocking for 30 pace making or defibrillation is provided from a remote distance.

Thus, the present disclosure sets forth a system which permits monitoring and delivering a controlled medical intervention for the patient who is waiting for emergency medical personnel to arrive on the scene. This can be especially helpful if the patient is unconscious or does not have 35 clear enough mental alertness to follow directions and no immediate help is available. Many lives can be saved through the remote medical

intervention which is accomplished by a centrally located personnel able to read and diagnose the heart originated signals form the patient and treat or direct it from a remote location.

The present disclosure is also provides patients the freedom which  
5 enables the him or her to be restored to normal mobility, i.e., out of the hospital and in the home surroundings. Normal life means different things for different people, but people feel more comfortable when restored to their normal activities. This reduces anxiety and seems to speed recovery from prior heart difficulties. The system enhances the liberty, and yet  
10 provides the assurances appropriate for the patient during recovery of available medical intervention. Moreover, the medical intervention can be highly tailored so that small difficulties as well as catastrophic circumstances can be dealt with until medical personnel arrive on the scene. It is one thing to summon an ambulance, but it is an altogether  
15 different matter to provide patient with directions on the phone about what is detected by remote on-line monitoring by trained personnel.

The present apparatus is summarized as a system and incorporates a method of medical intervention involving mobile patient.

The patient is equipped with the patient mounted sensors, signal  
20 conditioner and transmitter as set forth in the present disclosure. That transmits from the patient to a central antenna ideally connected with a receiver system to be described which present images on an emergency basis for purposes of intervention so that skilled and trained medical personnel can personally intervene. The intervention occurs at a distance.  
25 The equipment can be used to monitor the status of hundreds or thousands of patients at a given moment. Obviously, no single cardiologist will be familiar with all those patients and their medical histories. The present apparatus sets forth a system whereby patient data is stored in memory at the central location. The data includes all the data necessary to give the  
30 history of the patient, and includes patient heart signal wave forms to be used as a reference. In fact, data storage, organization, retrieval, indexing with cross referencing with a confidential coding system is an important part of this invention. Thus, even a cardiologist who is a stranger to a particular patient will readily see from the data stored in memory that  
35 quantity and type of data that is necessary to enable minor readjustments and major catastrophic intervention. All of this is presented in front of the

cardiologist supervising several hundred or several thousands remotely located patients. They are not lined up in any particular order but they are taken out of order based on emergency intervention requirements. When a signal indicating a change in the health of a patient is transmitted 5 to this facility, the cardiologist personally reviews the ongoing dynamic heart beat of the patient in real time and makes an intervention decision based on that. The monitoring station alternatively can transmit signals to a physician either on a digital pager or a cellular phone with graphic capability to display the electrocardiographic date. Thus, it a three way 10 communication between patient, monitoring station and a physician which makes present intervention helpful. Audio and video signals are also transmitted to all three to improve overall communication. Thus a signal can be transmitted back to the patient either from a monitoring station or from a physician. The patient is equipped with a monitoring system with 15 capability of initiating pace maker or defibrillator which is operated in any of several different modes to administer precisely what is required by the patient dynamically at the moment. The equipment can also be completely off, switched on to provide a pacing function, or in the event of severe fibrillation problems, it can be used as a defibrillator.

20 The patient is also equipped with a patient display which provides appropriate alphanumeric signals to the patient. If need be, the patient can also be equipped with an alarm which sounds for the express purpose of telling the patient that the patient ought to promptly, directly and without delay get to a medical facility. The patient may be five minutes 25 from a local or neighborhood medical facility. The trip to the treating hospital where the patient had bypass surgery may be much longer and time might not permit that kind of trip. In any case, the patient is provided with emergency instructions in an emergency situation. Another important feature is that the patient is provided a signal to administer 30 medications as needed. The device is preferably equipped with a small container delivering medication to the patient for quick treatment. Small tablets of nitroglycerin are effective when taken to relieve stress and difficulty. Nitroglycerin has a significant impact on patient's health. A more profound intervention is administering an injection into the 35 bloodstream of the patient. The patient is provided with a cardiac enzyme detection kit such as CK-MBS or Troponin analysis suggesting cardiac

damage. The patient is also provided with a detection kit analyzing oxidized LDL and modified LDL detection kit to further enhance the physician's ability to diagnose ischemic heart disease. A number of medications are also available which function as clotbusters. They are 5 most effective in reducing the harm of a heart attack which is triggered by formation of a clot in the heart. While the disclosure sets forth an automatic mode for doing this, it can be done directly and automatically or can be done by providing a signal to the patient whereby the patient injects the clotbuster medication with a small syringe provided with the 10 equipment. More will be noted concerning that hereinafter.

While the foregoing summarizes in general terms the features and operative equipment found in the present disclosure, and discusses in very general terms the mode of operation, the nature of the system and its method of use will be set forth in detail below.

15

## SUMMARY OF THE INVENTION

The present disclosure sets forth a monitoring system which is particularly effective for patients after discharge from a medical facility. This typically is applied to a patient after a myocardial infarction (MI), or 20 after heart surgery of any sort. Alternatively, the monitoring system can be applied to elderly patients who, on a regular checkup, have been discovered to have a cardiovascular decline which requires some change either by medication but at least involving some level of exercise and other treatment. For instance, with a patient of 80 years of age, it might 25 be appropriate to establish monitoring to look for measured data supportive of medical intervention by installing a pacemaker to change the heart rhythm. Another aspect may relate to surgery to correct valve action in the heart where the valve failure is episodic, and not otherwise chronic. In other aspects, the present monitoring system can be installed 30 and used with a patient for several weeks or months to safely conduct the patient to the end of an exercise phase during recovery. In this instance, a distinction is made between exercise for rebuilding and exercise at a maintenance level. In the latter instance, the restored vigor of the patient often enables the patient to be discharged from a maintenance program. 35 In other instances, it may be necessary to monitor that particular patient essentially for the remainder of their life.

As stated previously, the present disclosure also sets out a monitoring system which enables a patient to be monitored in a medical facility, typically including a CCU, and to be subsequently monitored upon being discharged to a regular room and then discharged from the hospital.

5 Alternately, it can be applied to a patient who develops a long term trend indicative of a slow loss of vitality. In any instance, this equipment can be applied to obtain monitored data of the patient over an interval of time so that the patient can be observed while within, or more typically away from the medical facility. Because the test equipment worn on the person  
10 is omnipresent, it becomes a matter of second nature and will become less stressful than the conventional visit to the doctor's office. Moreover, this enables monitoring of the patient while out of sight.

One aspect of remote monitoring is the difficulty of collecting all of the data and then observing that data dynamically. In the ideal situation,  
15 this collection and observation process should not be done by human intervention. To be sure, well trained cardiologists can recognize nuances not otherwise visible. While this may be the best analytical tool available short of a catheter, it cannot be used except when limited to hospital circumstances. In other words, it is an important data point which can be  
20 input so that the patient thereafter can be monitored with a continuing observation yet without the crucial attendance required at the medical facility. The present disclosure sets forth a monitoring system which can sound alarm signals without human intervention. Alarm signals presently exist where the heart rate exceeds specified limits, i.e., it goes below 60  
25 beats per second (BPS) or above 120 BPS. A more sophisticated analytical approach is obtained by the present monitor system. Further, the system of the present disclosure enables monitoring wherein the patients are able to go about their business to any number of places or facilities. They can roam far and wide. The monitor data are transmitted, by means of a  
30 transmission system, to a diagnostic system located at a home base. The amount of data transmitted is typically large, but can be compressed by means discussed in a subsequent section. As an example, a conventional spread of electrodes involves 12 electrode terminals attached to the body for a full spread of EKG signals. In effect, there is a base electrode for  
35 reference and 11 different electrodes connected elsewhere on the patient. The electrodes are connected at specific locations. The data can contain

systematic errors such as drift and base line shifts. The data, however, when dynamically presented on a cathode ray tube (CRT) or strip paper chart recorder, before the cardiologist, is visually corrected for systematic error by the cardiologist based on experience. For instance, there are 5 direct current (DC) offset errors that arise from lead connections. In a qualitative sense, the cardiologist can simply ignore that drift. The base line for a given signal will wander or drift. This is especially true during physical exertion by the patient. Some of these systematic errors derive 10 from perspiration, movement, respiration, changes in skin condition, changes in internal electrolyte concentration, and the like. The EKG signal again can be corrected visually by the cardiologist in attendance simply by looking at that and knowing the exercise state. However, the intelligence 15 to make this kind of transference is not so easily implemented unless the cardiologist is visually observing the patient.

15 There is another aspect that is significant in collection of a full spread of EKG data signals. The position of the heart within the body will impact the EKG measurements. This changes the response time lag between electrodes. In a real sense, it is fictional to represent the heart centered in the body. There are positional and displacement changes which occur from 20 patient to patient and which can even occur in the same patient over time. The patient may gain or lose weight. The patient's posture and muscular strength may change. Then, from one patient to another, the heart will be relatively displaced. The displacement includes a radial component, i.e., from the heart at the presumed center of the body radially outwardly to 25 the location of the electrodes positioned around the body of the patient around the thoracic cavity. All of these variations impact data reading. All these factors not only impact the data collected from a properly installed twelve electrode spread, but they also impact in ways that the cardiologist can accommodate when visually eyeing the patient but which cannot be 30 easily dealt with without substantial foreknowledge.

One aspect of the displacement problem should be noted. From patient to patient, the heart as a signal source relatively rotates. From one extreme to the left or right in one patient to another, this rotation can be perhaps 40° or even 50°. Rotation left and right is possible between 35 patients. Also, the heart can rotate upwardly or downwardly to present a different aspect. Viewing the heart as a signal source, the heart functions

as a finite vector source in space. In general terms, this results from the fact that the input signal to the heart starts the heart beat as a muscle contraction which ripples over the surface of the beating heart. While it has a finite beginning point at an initial instant, the flexure of the heart 5 during contraction ripples outwardly from that location, radiating over time in circular fashion. Distortions of the radiated ripple result from prior damage to the muscle. Suffice it to say, this kind of ripple effect on the surface of the heart (assumed to be spherical for easy discussion) results in a rotative shift of the heart from patient to patient. Again, the cardiologist 10 examining the patient personally and observing the strip chart recording in person can make the mental adjustments or "normalizations" necessary to read the set of signal traces describing the patient's heart functions. While easily done in person, it is not so easily done in practice absent the hands on relationship between the cardiologist and patient.

15 The present disclosure sets out a system which enables a large amount of cardiovascular data to be gathered, and yet which also compresses that data and reduces the data flow rate to that permitted by conventional telephone lines, i.e., a pass band of about 4 KHz. Data compression and redundancy removal are important aspects of this feature 20 of the invention. This involves the selection of desired signals which are different from patient to patient. More will be noted concerning that hereinafter. The present invention additionally enables monitoring of an important variable which is the oxygen content in the blood. The heart and lungs cooperate to refresh the oxygen level in the blood stream. This 25 is a highly significant data to the well being of a recovering heart patient.

The present invention is summarized as a telemetry system which enables a patient to roam far and wide and yet to be continuously monitored at a remote station. The monitoring system utilizes a multiple lead EKG spread, preferably 12 terminals, on the patient. The output 30 signals are provided to a signal conditioner and then to a multiplexer. The multiplexer is connected with an analog to digital converter. Preferably, the signals are digitally handled to reduce bias in the signals, to adjust the base lines of the signals, and then to perform a decomposition on the signals. The three foregoing steps are helpful to reduce signal bias as a 35 result of skin changes, change in base line, base line drift and the like. The decomposition step is involved in mathematically rotating the measured

data to take into account differences in heart position within the chest cavity. The signal is compressed, modulated and then transmitted. The patient also optionally carries a receiver with an alarm. The receiver is connected to a system adjustment circuit. That provides a number of 5 override signals. At a remote station, the equipment includes a receiver, demodulator, decompressor and then inputs the signal to a neural network. The neural network processes the measured data and presents the processed data to a data recorder. An alarm device is connected to offer it on a screen of a CRT. This enables human intervention. The human 10 intervention can then operate a transmitter to signal an ambulance or hospital in the event of an observed, critical abnormality of the measured or processed data. An alarm can be sent back to the patient. The remote equipment utilizes a receiver, demodulator, decompressor and neural 15 network which is input with selected presets, patient data and learning data so that the measured cardiovascular signals can be dynamically processed. This enables a cardiologist on duty at a central location to handle literally hundreds or thousands of patients, and to intercept data from each and every one of them, and to make a quick diagnosis based on their actual history and present needs. It also enables transmitting a 20 signal for instance to a hospital or ambulance to alert for an incoming situation and to also transmit a signal to the patient.

#### BRIEF DESCRIPTION OF THE DRAWINGS

25 So that the manner in which the above recited features, advantages and objects of the present invention are attained and can be understood in detail, a more particular description of the invention, briefly summarized above, may be had by reference to the embodiments thereof which are illustrated in the appended drawings.

30 It is to be noted, however, that the appended drawings illustrate only typical embodiments of this invention and are therefore not to be considered limiting of its scope, for the invention may admit to other equally effective embodiments.

35 The single drawing is a schematic block diagram showing the equipment used for remote medical intervention to administer care dynamically to a remotely located patient including heart pacing and

defibrillation as required.

Fig. 1 is a functional representation of the geometric location of the heart within a body, with respect to a reference location;

5 Fig. 2 is a vectoral representation of the location of the heart within the body in Cartesian coordinates;

Fig. 3 shows a block diagram schematic of an improved method of treatment of heart patients;

10 Fig. 4 is a schematic block diagram of apparatus and methods of the present monitoring system;

Fig. 5 is a conceptual overview of the major components;

Fig. 6 is a schematic block diagram showing the equipment used for remote medical intervention to administer care dynamically to a remotely located patient including heart pacing and defibrillation as required; and

15 Fig. 7 illustrates historical and current EKG signals from a patient displayed on two CRT monitors located at a remote monitoring and treatment facility.

## 20 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present disclosure is directed to a health monitoring system having special application to cardiac patients. It should be understood that the system can be modified to monitor patients suffering from other symptoms or diseases such as diabetes, high blood pressure, hypertension, 25 pregnancy, epilepsy and the like. Beyond that, it also is a monitoring system able to watch over and alarm or alert rapid medical intervention should the need arise and get help for the patient.

To set up part of the problem involved in this type monitoring, attention is directed to Fig. 1 of the drawings where a geometric 30 representation of a body of a patient is illustrated. This representation is tutorial. The patient is represented in symbolic form at 10. The trunk of the body is illustrated at 11 as comprising an elongate cylindrical member. This is idealized for tutorial purposes. The number 12 identifies several electrodes which are attached around the trunk 11 of the body 10. Some 35 of the electrodes 12 are placed on extremities including arms or legs as desired. The several electrodes 12 shown in Fig. 1 help make clear the

manner and mode in which signals are detected. The trunk 11 of the body 10, having the form of an idealized right cylinder, mounts the electrodes 12 at spaced distances from a heart H in the interior of the body 10. Again, for purposes of geometric positioning, the heart is represented as a 5 right cylinder 22. In actuality, it is not at all shaped like a cylinder, but it is more of a round sphere about the size of a softball. It is however easier to represent certain of the problems that arise with the heart position in the trunk of the patient's body utilizing the right cylinder 22 at H. The numeral 13 identifies a selected location on the heart at which a signal 10 triggering a heart beat is initially observed. The signal is located at a specific point on the heart. It propagates outwardly in a radius of curvature represented at 14 in Fig. 1. The radius of curvature grows until the signal propagates over the surface of a substantial region of the heart. In one sense, the heart serves as a signal generator which forms a signal at 15 a specified sequence. The right cylinder 22 representing the heart H is projected down onto a circular profile 15. The corresponding projection of the point 13 is on the forward point of that circle at a forward location. Assume for purposes of arbitrary description that this projected point, identified by the number 13", is precisely centerline of the chest of the 20 patient and is pointed directly forward. In that sense, the point 13" is located at that location which will be described as the zero reference point. This dimensional description is only a portion of the descriptive data locating the heart. More will be added later. The heart H can be mislocated so that the projection of the point 13 is located at 13'. The 25 included angle 23 between 13' and 13" can be as much as 40° or so. In other words 13' can be offset as much as 20° to the right or left from patient to patient. This describes a total included angle of about 40°. Even 50° has been noted in some situations.

Fig. 1 further includes a projection to the side of the heart along the 30 arcuate line 16. Here it will be noted that the side profile of the heart can show, and does show, that it may be canted with rotation to the right or left. The included angle 17 can also range as much as several degrees above or below the horizon which is drawn through the heart as a reference. The total variation of the angle 17 is upwards of about 40°. As 35 will be understood, the actual location of the heart with respect to both of these measurements can be expressed in the sum of the two angular

measurements 17 and 23 which represent the resolved orthogonal variation. The departure from the reference points can aggregate as much as 40° or 50°. In other words, the heart may be rotated to the right or left (clockwise or counter clockwise) and tilted up or down.

5 Fig. 1 shows the heart H represented by the right cylinder 22 on the centerline axis of the thoracic cavity of the body 10. It is assumed to be located on the centerline axis. There is a lateral distance to the wall of the body 10 indicated at 18. This distance should nearly be the same to the left or right of the heart H, and the distance to the front and back should  
10 be substantially the same for both. In actual circumstances, it is not always the case. Thus, the heart is subjected to angular displacements measured by the angles 17 and 22, and to lateral displacement measured by the dimension 18. Both are equally problematic in data collection and interpretation.

15 The heart in the patient shown in Fig. 1 is subject to another source of error. The thoracic cavity defines the location of the several electrodes 12 attached. The electrodes 12 are placed on the skin, not under the skin. The idealized thoracic cavity has a radius represented at 20, this being a solid line. In reality, the actual radius may be given at 21 where is either  
20 greater or less than 20. Again this will vary from patient to patient, and over time will vary with one patient. The patient may grow larger, gain weight or eventually lose weight. The shape may be distorted by other conditions such as the cumulative wear of bad posture, or other skeletal distortions. There is always a change in the shape for women patients  
25 during pregnancy. The diaphragm will typically move and reposition the heart and other components in the thoracic cavity. Thus, the thoracic cavity diameter idealized at 20 may change significantly. At least, the diameter varies from patient to patient.

30 The foregoing sets out a number of geometric induced, systematic problems that are encountered in reading EKG data. When the cardiologist is present and able to read the data in a strip chart recorder or on a CRT monitor while looking at the patient, and comparative readings are made from trace to trace, the medical specialist trained in reading that sort of data can make, on the spot, mental adjustments which take out problems  
35 resultant from distortions of this sort. If nothing else, the specialist has the option of repositioning a few, or perhaps several, of the electrodes to

get a dynamically corrected data. As will be understood, this can be done in a number of ways. The present invention, however, digitally processes the data so that the artifacts resulting from geometric variations in heart placement, angle of presentation and thickness of the body are removed 5 and the heart is moved mathematically to an idealized, or "reference" location. More will be said about this below.

Fig. 2 is a vectoral representation of the heart with respect to a "standard" or "reference" position as discussed previously in the geometric tutorial. The position 200 of the heart is represented by a vector 202 with 10 its origin at a reference position 204. This is useful in representing the heart beat, or signal source. Recalling the discussion of Fig. 1, The vector 202 is the sum of horizontal and vertical rotations, and horizontal displacement. More specifically, angle 223 represents the rotation of the heart in the horizontal (x-y) plane (see angle 23 in Fig. 1). Angle 217 15 represents the rotation of the heart in the vertical (z) direction (see angle 17 in Fig. 1). The displacement 218 represents the lateral displacement of the heart in the thoracic cavity (see dimension 18 in Fig. 1). The position 200 of the heart is, therefore, defined in three dimensional space by the vector 202 with its origin at the reference point 204.

Fig. 3 shows a block diagram schematic of an improved method of 20 treatment for heart patients having a wide range of difficulties. Two different problems are dealt with in Fig. 3. The first involves the sudden onset of heart difficulties, typically chest pain and ultimately involving a heart attack otherwise known as myocardial infarction (MI). The MI 25 occurs at 25. Typically, the patient is moved by ambulance to a medical facility. This is step 26. At the medical facility, the patient is normally placed in a coronary care unit (CCU) where the patient is kept on hard wired or FM telemetry connected leads. This step 27 lasts a few days or until the patient is stabilized. Suitable heart monitor medications are 30 administered along with blood thinners and the like. After a few days, the patient will be discharged from the CCU to a regular room and then to home care. In the interval when the patient is in CCU and sometimes when the patient is in a convention room but prior to discharge, they will be watched from the nursing station through FM telemetry but they will 35 ultimately be disconnected from that and sent home. The next step 28 represents that recovery step where the prescription may include

medication, but it also at least includes some rest and recovery. After a short interval, the patient will then be requested to report to an exercise room or other facility at the medical or other facility. Here, the patient will be put on a controlled exercise program beginning with very low levels of physical activity. The patient is monitored during this. The step 29 shows that monitoring continues throughout the exercise session. If the exercise session lasts 20 minutes to start, the cool down session may last another 30 minutes so that the patient is observed visually and typically by some form of telemetry. Vital signs may be taken before, during and after the exercise session. This session will be repeated several times a week, for instance four or five times per week. While beginning very gently, the exercise level will be raised and the performances required of the patient will be raised. This performance continues on as the patient continues to exercise with both visual and telemetry monitoring schemes.

Finally, the patient is graduated to a remote exercise routine. The step 30 shows the remote exercise sequence which is added. For instance, the patient may be discharged with instructions to walk two miles per day for five days per week in an interval of 30 minutes each time. The patient will be instructed to walk on level ground. Having done the equal to that in the exercise facility and especially connected with a monitor set forth in this disclosure, the patient will then have the confidence that they are not doing anything excessive or foolish risk a relapse. Moreover, the patient can then go forward with this remote exercise routine 30 away from the watchful eye of the medical personnel. The present invention, however, proposes to modify the step 30. Not only is the exercise carried out in a remote fashion such as walking two miles per day, the patient can do this while equipped with the apparatus of this invention which will be discussed in detail with regard to Fig. 4. Now, the patient is therefore able to be remote from the medical facility and exercise where it is most convenient to the patient. During this stage of the patient's recovery, they realize that repeated trips to the medical exercise facility is a heavy burden. They would rather exercise outdoors or in familiar neighborhoods. For a multitude of goods reasons, patient recovery seems to be better in a more normal setting away from the exercise facility. Perhaps the patient is encouraged by returning to normal circumstances of life. If nothing else, the patient is not faced with making the trip to attend to the exercise

session. Also, it is also important that the patient go about the remote exercise routine repetitively to build up their confidence in their body and to rebuild the assurance that they are not subject to a momentary relapse.

Again referring to Fig. 3, the procedure of the present disclosure includes the step 31 which involves patient roaming subject to the monitor. Here, the patient can go about a variety of duties. The geographic area for the roaming at step 31 is the area where the patient normally travels both for home activities and work activities. It includes stores and other businesses such as the post office. It can include trips to see friends and family. The roaming is carried out in the immediate vicinity so that the patient knows that, if an unexpected pain occurs, they can quickly return to the hospital or other health facility where they first received care. This time, however, they likely will be able to readmit themselves without an ambulance ride because they will be more alert provided they have stayed with the exercise routine. The step 32 shows the patient going about activities which are normal for that particular patient at that stage in life. They can do outside activities around the house and carry on normal activities with a minimum of intrusion as a result of the monitoring of the present invention. These steps, however, are deemed to be normal activities except that they are carried out subject to monitoring. Details of that will be given below.

In some instances, this procedure is implemented from other medical contacts. While the patient may not be struck down suddenly with MI hence requiring a ride to the hospital in an ambulance, the patient may nevertheless detect over a period of time that some thing is not quite going right. Fig. 3 shows an alternate step at 33 where aging or other gradual onset symptoms manifest, thereby prompting the patient to seek the assistance of a cardiologist or other health care professional. The symptom may be angina (pain) or sensation of an irregular heart beat. A cardiovascular diagnosis is made at step 34. This often will be done in the office or perhaps in a nursing home where the patient has continued to live, living well beyond the retirement age and up into the 70's or 80's years of age. If the patient does not have the sudden MI indicated at 25, the patient then can undertake some treatment at step 35 under control of the treating physician after the appropriate cardiovascular diagnosis and this treatment is undertaken typically with drug and diet care. After that

has been established as a solid regimen for the patient, the patient will then be instructed to undertake the appropriate rest and recovery step 28 previously described. Thereafter, the patient may be instructed in the same sequence of steps 29 through 32 previously described. As will be 5 understood, a person can enter either sequence depending on the condition of their health. The last three steps of Fig. 3 are discussed below.

Attention is now directed to Fig. 4 which sets out the apparatus of the present disclosure. Major elements of the apparatus consists of an patient portable system and a central coronary response system. These 10 elements enable the steps shown in Fig. 3 to be carried out.

#### PATIENT PORTABLE SYSTEM

The equipment worn on the person is on the left side of Fig. 4 and is indicated generally by the numeral 40. This equipment can be worn as a 15 portable device. It is not very large and can be worn at or on the person. It has a size enabling the device to be slipped into a pocket and hidden safely out of the way or attached elsewhere on the body.

In Fig. 4, the patient mounted monitor system 40 incorporates a set of EKG electrode terminals 42. In the preferred form, twelve electrodes 20 are installed, although that number may be reduced later as will be defined. Twelve electrodes are used to collect a full set of cardiovascular related signals. The signals are output from the twelve EKG terminals. The twelve electrodes are connected to individual signal conditioning circuits 44. These provide an appropriate impedance match, and input the signals 25 for subsequent processing. Some and preferably all of the twelve leads are connected through a multiplexer 46. The multiplexer has an input provided through a set of switches 48 so that different leads are switched on and off. More will be noted regarding that below. The patient can provide additional data and one such data is the measure of oxygen in the 30 blood. An ear canal O<sub>2</sub> plug 50 is mounted on the patient to detect the amount of oxygen in the blood. Ear canal detectors respond to a change in blood color and thereby provide an indication of the quantity of oxygen. Explaining briefly, the oxygen concentration in the blood is defined as 35 100% for the maximum value, with additional bands defined above 60, 70, 80 and 90%. In general terms, a healthy robust active patient will have a measure of oxygen of 90% or greater. A patient in the range of 60 to 70%

defines the fourth band. Measures below this band are generally associated with death. Effectively, this defines four bands. The topmost can be represented easily by a two bit binary signal such as 00. The next band which is in the range of 80 to 90% can be represented as 01, and 5 other bands are added to that definition. This provides relatively easily measured data which is important to the health and well being of the patient.

Continuing with Fig. 4, as noted the EKG terminals normally provide twelve data pads and they are connected to the switches 48. A switch 10 selector 52 is included with the patient to enable or disable selected ones of these electrodes. More will be noted regarding the number of electrodes involved in a sequence of operation. Assume for the moment however that all twelve signal pads are open from the signal conditioner 44 to the multiplexer 46. The multiplexer 46 provides an output to an analog to 15 digital converter (ADC) 54. The ADC changes the analog signals into sampled digital words. The sampling rate interleaving is controlled so that the data output is sufficient while avoiding a high level of redundancy. Consider as an example oxygen level in the blood from the sensor 50. Generally, that data changes slowly (except it is more dynamic in some 20 emergency events) and is measured periodically. The measured value is input through the multiplexer and then is converted into a digital word. There are four measured values permitted in the example just given. That binary data is relatively easily handled and does not need the ADC processing that is required for the heart beat monitoring. A bias correction 25 circuit 56 is included. There is the risk of measurement bias as discussed previously. Signals are defined between two of the electrodes. There is always the risk of a deviation or drift dependent on the nature of the skin. Skin conditions vary significantly. It is desirable that all the signals have about the same scale factor but this is sometimes somewhat difficult 30 because the skin on the same person can be quite different. Offset errors are substantial for those terminals 12 affixed to the chest cavity. These biases can sometime be eliminated, at least initially, at the time the electrodes are installed. In effect, a signal from one of the leads is observed over a time interval much longer than the period of the variable 35 being measured. This yields a "moving" average of the typically periodic variable being measured. A slowly varying change in the average is

indicative of a bias change. This "average" measurement is then subtracted from the measure of the periodic signal to reduce bias effects. The bias can arise as mentioned from a variety of skin conditions. Skin can vary depending on the location of the skin on the body (the skin is much 5 tougher in the palm compared to the earlobe). The skin can vary with dermatology of the patient, and can vary dependent on race, and exposure to outdoor climate. There are many other factors which impact the skin including the propensity of the patient to sweat, electrolytes of the patient and many other factors. Suffice it to say, DC offset as a result of skin 10 contact at the terminals has to be dealt with. While that can be done readily with visual observation, it is somewhat more difficult to do by a health care professional dealing with transmitted data. The anti bias circuit 56 essentially "corrects" the transmitted data for slowly varying bias changes after electrode installation on the patient.

15 The electrodes are subject to errors in addition to the DC offset just mentioned. The base line value will wander or drift. Such fluctuations are typically relatively slowly varying in time, and are induced by changes in patient perspiration, patient movement and respiration. Base line drift can produce misleading ST displacement in the EKG. ST distortion can lead to 20 false diagnosis of ischemia. This must be removed. It is desirable to accomplish this in a digital fashion so that a digital filter can remove the base line drift. The target for this is to implement a filter which has a magnitude response which is flat in the pass band and which possesses a sharp drop off on the flanks of the pass band to maximize suppression of 25 typically slowly varying base line drift, with reduced or no displacement of the ST segment as a result of drift. A relatively low frequency source of baseline drift, i.e., 0.4 Hz, can be removed for base line integrity. The base line drift according to the described filter is successfully removed. This is accomplished in the circuit 58 shown in Fig. 4.

30 Recalling Fig. 1 which shows the position of the heart in the chest cavity, it is subject to variation in position. There is a horizontal angular disorientation in one dimension, tilt or rotation in another dimension as represented by the curvature 16, and lateral offset represented by the radial distance 18. The orientation is illustrated vectorially in Fig. 2 in 35 Cartesian coordinates. As also noted, the chest dimensions can vary at 20. Heart position within the chest cavity of varying dimensions as described

with these four variables can impact the EKG signal measurements and produce error in interpretation. It is desirable to decompose the EKG signal into orthogonal components in the time domain rather than rely on corrections based the spatial orientation of the current source on the heart,  
5 which are difficult to determine. Recall that the periodic EKG signal of interest begins at a point 13 and propagates outwardly. Unprocessed data measured by each electrode will, therefore, exhibit maxima and minima in the time domain. The occurrence in time of a "peak" representing a cardiac function as measured by one electrode will typically be displaced, in time,  
10 from peaks representing the same cardiac function as measured by other electrodes. This displacement will be a function of electrode placements, and the orientation of the heart. If electrodes are placed in "standard" locations of the patients, then signal displacements in the time domain for a "standard" heart orientation will be known. Any observed perturbations  
15 in displacements are, therefore, attributable to "non standard" heart orientation. These perturbations are quantified and used to correct each electrode signal for orientation perturbations. The change from the spatial domain (as illustrated in Figs. 1 and 2) to the time domain in orthogonal coordinates adjusts the signal wave form measured by each electrode to  
20 present the data in a different aspect. This processing, in effect, rotates the heart to a desired centerline "standard" position at a fixed distance. This brings the EKG data to a common source and thereby fixes the criteria for measurement, observation, and interpretation. This decomposition step at 60 treats all the data from the multiple electrode leads as a group and  
25 normalizes the data to a standard geometry for interpretation. In non- mathematical terms, the heart as observed by the twelve leads is rotated to that the signals are orthogonal, and not subject to position distortion as previously described.

The decomposed signal from the circuit 60 is sent to a data compressor 62. Redundancy is reduced by the circuit passing only significant changes in the measured wave form data rather than the entire wave form, or by simply reducing the number of transmitted wave forms as will be discussed in a subsequent section. The signal is then provided to a modulator 64 and that is output to a transmitter 66. The transmitter 66  
30 sends a meaningful signal elsewhere. Significant benefits are noted with  
35 this transmission elsewhere as will be explained.

## CENTRAL CORONARY RESPONSE SYSTEM

Again referring to fig. 4, the numeral 70 identifies a central response system located away from the patient who wears the apparatus 40. The 5 central response system 70 is located at a medical institution which, for instance, has a full time cardiologist on duty day and night. It could be located in a large metropolitan area so that it can provide monitoring services to any number of patients. Presumably, things will go smoothly for any particular patient on any particular day; nevertheless, with 10 hundreds or perhaps thousands of patients undergoing monitoring, the emergency attendants at the central facility are on duty. Cardiologists tremendously assist in providing medical intervention. Just as importantly, the system 70 is a device which will be described with "unmanned" 15 operation which continues to monitor the patient wearing the equipment 40. In this aspect, it works day and night and will not be interrupted should trained personnel not be physically present. The equipment 70 includes the receiver 72 which is tuned to the frequency of the transmitter 66. This transmitted signal at the receiver 72 is one of many. The segregation of individual transmitter signals will be discussed 20 below. The receiver 72 outputs the received signal to a demodulator 74 which then provides the signal to a decompressor 76. So to speak, these recover the signal and restore it to a condition which represents the output of the twelve lead terminals placed on the body of the patient. It is, however, modified in several important aspects which should now be 25 noted. The transmitted and recovered EKG signal at the receiver had been shifted. The shift takes into account variations in position for the patient as presented in the discussion of the decomposition system 60, and with regard to Figs. 1 and 2. Tilt and rotation of the heart with respect to the chest cavity is reversed. Not only that, the heart spacing to the side wall of 30 the cavity is corrected. Further, the signal from the large spread of leads is reduced in terms of redundancy with the circuit 62. Explaining, there are twelve leads in a typical spread of electrodes to conduct an EKG test. Usually, events occurring in the heart are periodically reproduced at several different electrodes. They may show different aspects of the same 35 event but the different electrodes provide that signal from a different perspective and therefore the data from the twelve leads includes a

significant amount of redundancy. Once the patient has been placed under medical care, the nature of the ailment and the anticipated wave form indicative of difficulties will be predictive so that the number of leads can be reduced. While twelve electrodes are required at an initial condition, 5 the number of active leads for monitoring can often be reduced to a lesser number. Consider for instance a patient who is subject to an irregular heart beat. That signal in the QST wave form is readily understood and recognized. With the history of the patient, the number of specific EKG leads can be reduced perhaps to four. This is implemented in the patient 10 mounted equipment 40. Returning now to Fig. 4, the switches 48 are interposed between the twelve EKG terminals and the modulator 46. Several of the switches 48 can be opened. A switch selected 52 is provided for that. Assume for the moment that the patient is equipped 15 with twelve leads. The switch selector 52 is set to open a selected number of these signals thereby interrupting those signals because they are not needed. In effect, redundancy is reduced. The switches 48 are also subject to control of a system adjust circuit 68. The circuit 68 is provided with a received signal from the receiver 78 in conjunction with an alarm 80. The system adjust circuit is provided with digital word instructions 20 which are decoded by it to change the switches 48 to drop one or two of the terminals so that redundancy is reduced and yet the crucial signal for the care of that particular patient is nevertheless processed through the multiplexer and other components for transmission. Thus, the twelve leads may be placed on the patient at the time of discharge from a medical 25 facility, the switch selector 52 is then operated to reduce the twelve to a steady state operation for maintenance with six of the signals provided, and then in the event of difficulties, the system adjust circuit 68 is operated to change the status of the switches 48 thereby receiving data from ten of the EKG leads. Or, perhaps only three leads are sufficient to 30 send the needed data for that patient.

Again referring to Fig. 4, the receiver 78 is keyed to receive an encoded message. The encoded message carries with it the identification of the particular patient 40. The patient wearing the equipment 40 may have difficulties without even knowing that difficulties have arisen. For 35 instance, an alarm condition may exist requiring the patient to quickly go to a medical facility. The alarm 80 is included for that purpose. Otherwise,

continuing adjustment of the operation of the equipment 40 can be provided. The switches 48 can be toggled, and the operation of the multiplexer 46 can be changed also. In like fashion, the bias removal circuit 56 and the base line adjustment circuit 58 can be modified or 5 altered. Other aspects of the system including the decomposition circuit, data compressor and modulator can be remotely controlled as desired.

Going back to the central medical facility, the decompressor 76 provides the recovered unique signals from the patient to a neural network 82. The neural network is provided with a set of learning data 10 from a data source 84. The particular patient wearing the equipment is tested several times, typically before the equipment is installed and that is represented as patient history which is input at 86. The neural network 82 is provided with appropriate presets 81 also. The significant aspect of this is the neural network operation. A neural network is defined as a 15 system processing device typically having the preferred form of a software package which processes data. The teaching data is input so that the neural network learns and thereby reaches the right or correct decisions. A neural network typically has a first set of input terminals and a connected set of output terminals. In between, there are one, two or three 20 layers of decision making nodes. The number of layers of nodes can be varied and the precise number of nodes in each layer can also be varied. A neural network is then provided with a set of learning data. This is used to teach the system. As an example, data from patients having a healthy EKG signal is input. Of necessity, there will be a range of data which still 25 nevertheless represent the EKG signals of healthy patients. The neural network is also provided with EKG signals from patients having difficulties. This enables it to learn how to recognize the medical problems. Mitral valve relapse is an example. That data can be input and stored so that the neural network will recognize that problem when it repeats. The neural 30 network thus detects and classifies any patient arrhythmia. Preferably, the neural network 82 is trained with a data base indicative of several types of arrhythmia which is furnished by the American Heart Association (AHA). So to speak, the irregularities indicative of arrhythmia for a given 35 input data for one patient prompts the neural network to recognize the error (meaning the departure from normal) and to propagate that to the different levels of the neural network. Typical classified disease categories

include several types of biventricular hypertrophy, many types of myocardial infarction and other disturbances to heart rhythm and signal propagation in the heart.

Through the use of the teaching data from the AHA, various types of heart irregularities signaled by the departure from the standard EKG profile provide an alarm condition interpreted by the neural network 82. Interestingly, the equipment at 70 of Fig. 4 responds to the neural network 82 by forming an output signal on an alarm device 88. At that time, the signal from the particular patient prompting the alarm condition is displayed on a cathode ray tube (CRT) 90 for skilled personnel observation. Here, the cardiologist optionally can come into play by looking over the particular reconstructed EKG signal prompting the alarm. The data are also input to a data recording 92. It is stored and later transferred to memory 86 storing the patient data where it will become a part of that patient's medical history. As part of the system, either automatically upon the sounding the alarm 88 or upon specific approval by the intervening cardiologist, a transmitter is operated. A transmitter 94 sends a signal back to the receiver 78 on the patient. Several things can be accomplished with this signal dependent on the instructions input to the transmitter 94. The cardiologist is provided with an override keyboard 96 so that a particular transmitted signal can be provided directly to the cardiologist to the transmitter 94. The keyboard 96 enables override signals to be created. These signals also are used to change the mode of operation of the patient mounted equipment 40. For instance, the redundancy can be changed completely by resetting the switches 48. More data can be input so that the cardiologist can require transmission of signals from all the leads on the patient. Assuming that twelve are present, all twelve can be operated. The switches 48 are reset to accomplish this. Adjustments also can be made in the bias circuit 56 and the base lines of the signals can be changed by the circuit 58. All this can be controlled remotely. These changes can get carried out without alarming the patient because the patient does not necessarily sense, feel or know that changes are being made to equipment so that more detailed monitoring is then being obtained. On the other hand, the cardiologist can send or not send an alarm condition to the receiver 78 for sounding the alarm 80 to the patient. If that is done, it typically will involve instructions to proceed to a specified medical facility.

Certain aspects of data transmission between the patient mounted system 40 and the remote system 70 should be noted. They can be a few hundred yards or many miles apart. However, so the patient can undertake normal living activities, the patient typically is discharged from the hospital and the equipment 70 is operated from the facility to monitor the patient. The distance may vary quite widely. The equipment 70 can be located at the geographic center of a large population for easy monitoring. Alternatively, the receiver 72 can be equipped with a tall antenna while the receiver itself is located at a remote location. It is possible for the patient to carry the equipment 40 over some distance. Again referring to Fig. 4, the numeral 100 identifies certain components which are used to enhance the range of patient movement. Assume for the moment that the receiver 70 is provided with an antenna that is located at the center of a downtown area and that the population is concentrated around that area. The centralized equipment 70 may have sufficient range to accommodate patient movement of five or ten miles. If the patient moves further out radially, it may be necessary to use repeater stations or other equipment in between. The equipment shown at 100 illustrates similar repeater stations 102 and 104. They have transmitter and receiver pairs which enable the system to receive the transmitted signal from the patient mounted equipment 40 and to transmit that even by greater distances. Thus, the repeater stations 102, 104 and perhaps more are scattered around geographically to provide adequate coverage even at a great distance from the central receiver 72. If need be, they can be connected together through a telephone system 106 which in turn takes care of the long distance transmission. The telephone system 106 can be connected also to the receiver 72 if desired. The communication equipment 100 also includes an optional synchronous satellite 110 equipped with a transmitter and receiver combination so that it also operates as a repeater. In that sense, it functions in the same way as does a satellite pager system. The signal can be transmitted from the patient 40 up to the satellite 110 and from there transmitted down to one of the repeater stations or directly to the receiver 72. The equipment 70 thus can communicate directly to the patient mounted equipment 40 or can take advantage of the repeater system.

One added link that may be helpful is to provide the intervening

cardiologist with a transmitter 112 which transmits directly to the emergency room of a hospital. A receiver 114 within the emergency room is tuned to the transmitter 112. Automatically or by intervention of the cardiologist, the patient can be sent a signal instructing the patient to 5 report immediately to a staffed hospital emergency room having appropriate cardiology assistance. The patient who is experiencing chest pains may want to go to the nearest hospital. However, that hospital will not know that they are coming. Moreover, they may or may not have readily available medical assistance and facilities so that emergency 10 treatment might be delayed. Therefore, the equipment either automatically or through the intervention of the cardiologist sends through the transmitted signal to the patient support equipment 40 an instruction noted at the receiver 78 and which provides an output on alarm 80 instructing the patient to go to a particular treatment facility. It may not 15 be the closest, but in terms of health, the instruction may tell the patient to pass by an overcrowded emergency room and go to a facility where help is ready to meet the patient literally at the front door and to undertake treatment immediately. Through this approach, the patient is sent to the correct location. Moreover, with the intervention of a cardiologist, or 20 automatically through the operation of the neural network 82, the transmitter 112 is provided with an input indicative of the nature of the problem. That is transmitted from the transmitter 112 to the hospital receiver 114. The coded message will identify the patient, the instructions given to the patient, and tell the hospital through the receiver 114 that the 25 arriving patient is having a specific problem as indicated by the EKG. Several options can then be executed.

Going back to Figs. 3 and 4, it was noted that the patient is permitted to roam subject to the monitor and undertake normal activities at the step 32. In the event the patient perceives difficulties, the patient has an 30 instant feedback system whereby the alarm device 80 provides instructions to the patient. Great peace of mind can be achieved if there is a pain, followed by that uncertainty in the patient and yet the equipment 40 operates successfully, transmits a signal and receives a signal back that the pain is not a significant event. In effect, the pain becomes a false 35 alarm 36 and the patient is provided with a signal indicating to the patient that nothing need be done. While that decision might be made by the

patient acting alone, when made with the assistance of this remotely located equipment and testing competency of the sort described in this disclosure, the patient has a distinct advantage when receiving the false alarm signal 36 indicated in Fig. 3. This, however, is instructed to the 5 patient in an affirmative way. It is a signal saying far more than simply do nothing. Rather, it is a signal instructing the patient that doing nothing has been evaluated and is the wise decision. Separately, medicines literally in the pocket of the patient comprise immediate treatment undertaken wherever the patient is located. That is indicated at 37 in Fig. 10 3 as the home treatment. The home treatment may be as simple as taking by mouth the typical nitro dose which reduces heart pain quickly. The third option is transmission of an instruction 38 to the patient to go quickly to a specific hospital emergency room entrance. This protocol may be required as a result of EKG data analysis.

15 Going back to Fig. 4 of the drawings, it will be noted that the patient mounted apparatus 40 stays in two way communication with the central medical facility 70, which is typically remote from the hospital containing the receiver 114. The aspects of the medical facility 70 that are especially important include the provision of an antenna of sufficient height to 20 receive the signal for the receiver 72. The neural network 82 provides the interpreted EKG data and significance of that data. The alarm condition indicative of medial difficulties is transmitted automatically, but is subject also to review by an attendant cardiologist if desired. This intervention 25 can materially shorten diagnostic times in emergency conditions so that patient treatment has started sooner and precious time is not lost.

The quick response of the present system is noteworthy. In real time, emergency medical conditions are signaled. This can start real time medical intervention. The patient may have only a short interval in which to deal with emergency conditions. One example of this is clot formation in 30 the heart which event is signaled from the patient. Once the clot is identified, it may be appropriate to send a signal to the patient to intervene quickly by the administration of medications which dissolve clots. Such medications are most effective if administered within the first few minutes after the clot has formed. It is common that efficacy of these 35 medications is seriously degraded if intervention is delayed by more than about 120 minutes. Clot dissolving medications are most efficient when

quickly administered.

The data processing aspects of the present disclosure are limited by the data transfer rates entailed in the system. It is desirable that the multiplexer 46 be operated at a rate of about two times faster than the highest frequency component desired from the EKG signal. The Nyquist criteria in connection with the AHA definitions require sampling at least at a minimum rate just given. This sampling rate dictates the amount of data output from the spread of electrodes. In turn, the system provides the appropriately modulated RF transmission. That delivers a very large amount of data, i.e., the data transfer rate is quite high. The data transfer rate in perfect conditions might exceed about 50 kiloHertz (kHz). However, data transfer rates of this sort cannot be handled without some reduction in the data by reducing redundancy, etc. Probably the most limiting connective link reducing data content is transmission over conventional telephone lines. They are typically limited to about 4 kHz. Taking this constraint into account, the data compression scheme and the reduction of redundancy in the patient generated signal preferably provides a transmitted signal with this data content. In other words, the modulating signal encodes the signal so that it will pass through a telephone system.

The equipment 40 on the patient is preferably quite small. It can be mounted in a small container about the size of a pager. The patient observes the alarm 80 which is preferably at least a visual alarm. A readable screen or Liquid crystal display (LCD) characters provides one suitable version. Other versions output a signal so the patient can look periodically at other LCD screen and be reassured that the prevailing conditions are indicative of good health. When the problems arise, the patient may or may not have physical discomfort. If discomfort occurs, the patient is reassured by the signal on the LCD alarm 80.

### 30 Base-line Drift and DC Bias

Yet another salient feature of the invention is its capability in suppressing undesired frequency components without affecting the integrity of the desired signal. These components, as previously stated, may arise due to electrode to skin direct current offset, muscle tumor, slippage of electrodes, breathing and patient motion in general. This (i.e., filtering) is accomplished by the compression scheme mentioned

previously as a bonus or a bi-product. As stated earlier, the inherent features of the compression scheme used herein is its capability of resolving signal content in time and frequency. This feature (transmission prioritization based on isolation and selectivity in time and frequency) 5 offers great latitude in assigning low weight to the transmission coefficients that correspond to the undesired frequency components. This virtually precludes the need for the necessary filtering required on most biomedical data after acquisition and hence preserves the integrity of the significant signal components.

10

#### DESCRIPTION REGARDING FIG. 5

Attention is now directed to Fig. 5. In general terms, the equipment on the left side of the schematic block diagram is located on the patient. To the right side, the equipment is located at a remote medical facility. It 15 is a facility which will be termed a "remote data bank" along with an available physician. It need not be a hospital in the classic sense of the word; typically it is a set of equipment which is located with an antenna that is relatively tall for easy communication from a central point in a large metropolitan area. Because most of the equipment is electronic in 20 nature, it can be located there or it can be connected by remote lines from the antenna. It includes also a facility where skilled cardiology personnel are available. To that end, it will be described as the electronic diagnostician. The remote electronic diagnostician (RED below) can literally administer and implement life saving measures in emergency conditions so 25 that patients in postoperative or post attack recovery modes have a far greater chance of restoration to full health. The patient supported equipment, on the left of Fig. 5, will be referred to generally as the patient equipment and is denoted by the reference numeral 210. That equipment is set forth in the above referenced patent disclosure which is incorporated 30 to enhance the details of the present disclosure. The patient supported equipment 210 communicates with the RED equipment. That is generally indicated by the numeral 260 and again is located on the right side of the drawing.

The patient is equipped with a set of patient sensors 212. Again this 35 portion of the equipment is set forth in the above mentioned disclosure. The electrodes 212 provide signals which are ultimately converted by a

signal converter 214, and those signals are transmitted by a transmitter 216. Details again are incorporated by reference. In effect, the state of affairs of the heart of the patient is transmitted to the remote location, that is, signals are sent to the RED 260. The transmitter 216 communicates 5 with the receiver 262. The receiver 262 responds to the transmitted signals and delivers the signal to a demultiplexer 264. The demultiplexer 264 is provided with two general types of signal, one being the digitized and encoded heart signal. That is output by the demultiplexer 264 to a digital analog converter 266. That enables reconstruction of the heart 10 signal. Another portion of the received signal includes patient ID numbers which are separated by the demultiplexer 264. These patient ID signals are noted by the ID detector 268. That helps identify this particular patient so that data regarding this patient can be fetched.

Assume for purpose of description that the RED 260 is monitoring 15 10,000 patients on a given day. For each of the 10,000 patients, appropriate medical data is stored in digital form. Obviously, this would include patient name, address and regular treating physician. Beyond that, it should include a lot of information on the medical history of the patient 20 age, health and general condition should be included. All of this can be captured in digital form because it generally has an alphanumeric aspect. That is available from the memory 270. In addition however the memory 270 preferably stores signal wave forms from this particular patient. These signal wave forms are captured when the patient is undergoing 25 medical treatment. These wave forms will serve as a baseline for comparative purposes. For instance, an otherwise healthy patient may suffer a sudden MI, and then be hospitalized. There is no "normal" baseline for that patient because the patient was healthy before the MI event. Fortunately however a lot of monitoring will go on while the patient is in the hospital and recovering. Representative signals from the 30 heart are captured often. As the patient makes a recovery sufficient to be released from the medical facility, an ensemble of heart signals will be collected and stored. Three or four cycles of the heart are thus stored, for each occasion. For instance in a convalescent interval of one month, the patient might provide ten or fifteen different wave forms over that month. 35 Each is taken from a desired point of view with respect to the heart with an appropriate set of electrodes. These collectively form a library of EKG

signals which are in the memory 270. These are kept available so that the event which triggered hospitalization in the first instance is captured in some measure, and the recovery of the patient in the next few days is also captured with representative EKG signals. This ensemble of EKG wave 5 forms is stored and made available in the memory. The memory 270 thus stores the alphanumeric data of a biographical nature and medical background, along with the dynamically collected EKG signals. All of this is available for later recall.

10 The patient ID signal received at the RED 260 is used to sort through the memory 270 and to find the data for that particular patient. That data is then output and delivered to the memory select circuit 272 which rejects all the other data in the memory 270.

15 The retrieved memory data for that particular patient is recovered and is displayed on a CRT 274. That is historical data which is important for medical treatment. In addition to that, a CRT 274 makes a display of the dynamic EKG signal from the patient. This signal is delivered through the demultiplexer 264 and is then converted into an appropriate analog signal wave form by the DAC 266. The DAC cooperates with an alarm 20 system 278 which forms a signal for the medical personnel and which also connects to the select circuit 272 so that signals which are pertinent are obtained from the information stored in the memory 270. More 25 specifically, it may be very important to look up the prior time the patient was treated, if any, with a clotbuster medication. It may be very important also in an alarm condition to examine the blood thinners administered to the patient previously. Clotbusters reduce the clotting of the blood system. This change in clotting factor can be problematic if added on top of prior administration of blood thinners such as aspirin or Coumadan. The alarm thus prompts the memory select circuit 272 to display the related signals tied to the alarm condition.

30

#### VARIETY OF MEDICAL CONDITIONS

35 The installed equipment 210 on the patient is able to detect and respond to a variety of conditions in the patient. Three examples are noted to suggest the variety of conditions that can be handled by this apparatus. In the first instance, assume that the patient suffers from a declining heart rate. This usually occurs without pain or manifestation

other than that the patient may have cold hands or feet, or perhaps some other evidence of a lack of blood flow. The second condition is similar to the first in that the heart rate might be somewhat high. Representative numbers for a given patient will vary from day to day and time to time.

5 However, it is possible that the heart rate will become either too low or high as just noted. In the first and second examples, the system set forth in this disclosure enables diagnostic review by a remotely located professional able to evaluate the health and status of the patient. The intervention then selectively provides the desired heart rate. This is  
10 transmitted to the patient and serves as a pacing function. The pacing function regulates the heart rate. It delivers heart pacing pulses at a desired rate. Assume that a low value is in the 50's while an unduly high value is in the 80's. The peacemaking function may provide seventy-two beats per minute (BPM). That will be developed below. As a third  
15 example, assume that the heart goes into irregular fibrillations. Not only is there a cessation of regular beats, but the fibrillations usually occur at a rate of over 100 BPM; a defibrillator shock pulse is administered; assume that the first defibrillation pulse does not work; then a second and third will be administered. Examples of this will be given below also.

20 The equipment at the patient should now be reviewed in some detail. The patient is provided with a pager 220 which is integrated into the equipment. The pager includes a receiver 222 which received digital coded messages. The receiver 222 recognizes transmissions intended for that particular patient. Any message which is sent to the patient is then  
25 recognized by the decoder 224. That is connected to an output device 226. commonly, the output device is an LCD display which provides a specified number of characters.

These provide instructions to the patient. As an example one instruction might simply be that the patient should rest. Another instruction of value is that the patient is doing well. It is especially important for the patient to have this available on the display 226. If need be, the display can provide an output of the actual heart rate such as 60 BPM. To let the patient know, the pager 220 incorporates an alarm 228. The alarm sounds in a way appropriate for the patient prompting the  
35 patient to look at the display 226.

The equipment at the patient also includes the peacemaking

equipment 230. This typically is a bought item. This includes a power supply 232 which is provided with electrical power by a battery 234. It is connected with a pulse circuit 326. The pulse circuit has an output to a set of electrodes 238. The electrodes 238 are positioned on the body of a 5 patient to form necessary pulses which are experienced by the heart and which change the heart operation. At bottom, the heart is electrically triggered by small electrical impulses occurring in the heart. The electrodes 238 are positioned on the body so that the pulses generated by the pacemaker device 230 accomplish appropriate timing of the heart in 10 operation. More will be noted concerning this.

The patient is also equipped with a medication system 240. This operates in conjunction with a reservoir 242 and a suitable pump 244. Medication is delivered to the patient from the reservoir 242 through the pump. Operation of this medication system can be accomplished remotely 15 or locally. However, the operation needs to be timed or coordinated. The receiver 222 receives an appropriate message. The output of the receiver 222 is delivered to a clock driven decoder 246. As appropriate, the decoder 46 sends a signal to a pulse select circuit 248. That controls the peacemaking device 230. The decoder 246 also controls the medication 20 system 240.

Going back now to the equipment conveniently available at the central facility 260 and especially the equipment which is used to intervene, the treating medical person is equipped with a keyboard 280 and is able to type in instructions. These instructions are sent to an 25 encoder 292 and then the transmitter 284. The transmitter 284 is linked to the receiver 222. This closes the loop which was initiated by the transmission from the transmitter 216 to the receiver 262. When a reply signal is transmitted back to the patient, the signal carries with it the appropriate patient ID coding so that only the intended patient responds. 30 A unique handshake signal is included to assure security in transmission. Moreover, the secure transmission is observed at the pager 220, is recognized, and a suitable signal prepared by the medical person is displayed on the pager. Often, it is a signal simply mandating that the patient be calm and that nothing is amiss. That signal alone when 35 appropriately perceived by the patient will have a salutary effect. Moreover the medical person has the control so that the patient signal,

then displayed along with historical signals for that patient, are both viewed by the treating physician, who can then intervene. Assume for the moment that a change in pacing is required. Should the patient be suffering from a heart rate which is not appropriate or which is perhaps 5 unstable, the signal can then be sent to impose a pacing function such as 72 BPM. This signal is transmitted. The display 226 will indicate this occurrence to the patient. Moreover, the decoder 246 will observe this instruction and provide an appropriate instruction to the pulse select circuit 248 which prompts the peacemaking device 230 to apply the 10 regulated pacing pulse. In this instance, having selected 72 BPM, that type of instruction and assurance is provided to the patient. It will be understood that the pager 220 displays the event but the event is under control of the physician- located remotely from the patient, and is not under control of the patient, thereby avoiding self-diagnostics. This gives 15 the patient a greater sense of confidence. It may also give the patient comfort and assurance as the pacing device 230 is operated. To the extent that an electrical impulse is pressed against the skin of the patient and some discomfort is felt, curiosity may be aroused. That curiosity is satisfied by providing the display 226 with an instruction that the pacing 20 function has begun. The decoder 246 is operated in conjunction with a clock so that it is able to pace events. It is triggered so that the pacing function is continued for a designated interval. Perhaps only one or two minutes is necessary; then again, it may require pacing for the entire day while the patient is up and moving about. The pacing function may be 25 switched off at night to cite a change in operation. In any event, the patient is provided with the appropriate display instruction and assurance.

Assume that the patient experiences a measure of angina. If need be, the system is then triggered to deliver medicine appropriate for reducing the angina discomfort or pain. Patient's blood pressure, 30 respiratory rate, blood oxygen content are also monitored and transmitted to the monitoring station and/or to the treating physician. This is administered to the patient in one or two forms. If need be, the reservoir 242 is filled and the pump 244 is operated to dispense an appropriate measured liquid quantity. In the event of angina, a common treatment is 35 nitroglycerin taken in pill form under the tongue. The reservoir in that instance can hold a specified number of individual pills which are

dispensed. The alarm 228 is sounded. The display 226 is then provided with instructions to take one or two from the dispensing equipment, and the patient can then simply administer these by hand.

More sophisticated drugs are occasionally required. The patient may 5 have a clot form in the heart region. Often that will provide a signal well in advance of pain. The signal can be transmitted from the patient through the equipment 210. An alarm condition is noted by the treating physician at the remote facility 260.

When the RED receive this signal and goes into action, they transmit 10 back an instruction to the patient to administer the clotbuster medication. The clotbuster medication is significantly effective when administered within about 100 minutes of onset. The value of it is reduced significantly as the clot becomes older. The reservoir 242 can be provided with this. In some instances, the medicine dispensing mechanism 240 is connected to 15 the patient so that the injection occurs automatically and directly into the bloodstream of the patient. This typically requires the implantation of a s hub into a blood vessel or at least under the skin, depending on the type of injection. In this particular instance, that kind of installation can be accommodated. In another aspect, the reservoir 242 may hold the 20 clotbusting medication in the form of closed and sealed ampules. It is delivered out of the reservoir by sounding the alarm 228 and the means 242 delivers the container so that the patient then can use a disposable syringe to make their own injunction. The clotbusting mechanism administers the medicine appropriate into the body of the patient. This is 25 accomplished after the medical personnel has verification of clot formation, and the time lag is markedly reduced.

In some instances, the system is used to provide defibrillation. Some difference in operation should be noted. In a pacing function, pulses are provided steadily for a long interval, perhaps 72 BPM over five or ten 30 hours. Indeed this can last for days or weeks. The heart pacing function requires pulse which are quite small. At some appropriate rate selected by the medical personnel, heart pacing pulses have minimum power in the pulses. The power in a given pulse is relatively uniform and is quite small. The power is measured in milliwatts. The milliwatt pulse transmission is 35 periodic, having a pulse size and shape which is determined by the pulse select circuit 248. Assume for purposes of description that the pulses are

at their requisite level to be felt by the heart, in which event the pulse amplitude and pulse width are adjusted remotely of the pacing device 230. In a significant contrast, the defibrillation pulse mode is altogether different. There, a little threatening condition may be encountered. The 5 heart is inflicted with a very substantial high energy pulse. Assume for purposes of discussion that the high energy pulse has a peak power 230 watts. This might involve the formation of a pulse at 100 volts with a current of 0.3 amperes. While the duration might be short, a pulse of this size is a significant volt. Because, life threatening conditions have occurred, 10 it may require a pulse that large. Even though the pulse is large, it may or may not restart the heart in the desired fashion. Assume that it is medically appropriate to wait eight or ten seconds to see if the heart will return to the desired heat rate with the desired wave form. If that occurs 15 there is no need for a second pulse. If it does not happen, it may be essential to administer a second defibrillation pulse. If a pulse of 30 watts was first attempted and did not succeed, then a second pulse at perhaps 10 or fifteen seconds spacing is needed and it should be much stronger, i.e. an increase of 25% to 50%. As the system administers that second pulse, again there is a wait of perhaps 5 to 15 seconds to determine whether or 20 not fibrillations have stopped and conventional heart rhythm has begun.

The medical personnel intervening in this situation may be monitoring hundreds, even thousands of patients and may not know the desired pulse level for the defibrillation shock. As an example, the defibrillator electrodes which normally provide pacing signals are now 25 called on to deliver a stronger shock to the heart. The amount of shock required will vary from patient to patient. At one extreme consider an elderly woman who has a body weight of less than 100 pounds and has substantially no body fat. Assume further that this patient has relatively thin skin. A massive jolt is not normally required for this patient in 30 comparison with a younger man who has significant body fat and whose skin is relatively thick. A larger jolt is required. The medical personnel handling the situation may not have enough time to review body measurements recorded in the file. To that end, the memory 270 is provided with sufficient data to indicate a suggested defibrillation pulse 35 magnitude. The memory 270 stores this. This is a data which is predetermined by variables just noted, namely patient weight, body type,

skin thickness and so on. In that instance, the memory 270 delivers the data and displays it on the CRT for any medical person to see. By that approach, the initial jolt is tailored. That initial jolt is sent to the pulse select circuit 248 by appropriate instructions. This is used to shape the 5 pulse, thereby determining the power delivered.

In alarm conditions such as that just noted, the medical personnel is preferably provided with an additional encoder 286 which is connected to another transmitter 286. That transmitter is set to a frequency to summon an ambulance from the local emergency service (EMS) provider(s). The 10 signal transmitted to the ambulance service includes encoded data from the keyboard 280. It can include the name and address of the patient. It can also include appropriate demographic information and emergency medical instructions as appropriate. These can be provided to the ambulance which is normally operated by suitably trained emergency 15 medical service (EMS) personnel. When the EMS personnel arrive at the location of the patient, they will be preinstructed with all sorts of data and information to enable them to quickly and directly begin their medical intervention. They will not be left to guess; they will be receiving data and instructions at least once and perhaps continuously after intervention 20 starts by the EMS personnel

The present apparatus sets forth a device which enables a post operative or recovering MI patient to be treated and restored to a substantial level of health.

While the foregoing disclosure is directed to the preferred 25 embodiment, the scope is determined by the claims which follow.

What is claimed is:

## CLAIMS:

1. A method of monitoring the cardiac status of a cardiac patient permitted to undertake normal activities comprising the steps of:
  - (a) attaching a set of electrodes to a patient to enable normal activities;
  - (b) forming a set of time dependent signals from the set of electrodes;
  - (c) time multiplexing the signals;
  - (d) converting the multiplexed signals into digital values having a data rate;
  - (e) reducing the data rate while observing patient cardiac condition at the reduced data rate;
  - (f) transmitting the reduced data rate of the patient cardiac status;
  - (g) receiving at a central location the transmitted reduced data rate;
  - (h) wherein the steps of transmitting and receiving are limited by the pass band of a connective link between the patient and the central location;
  - (i) storing heart beat signal shape and condition data of the patient at the central location;
  - (j) electronically comparing the received reduced data rate of the patient with the stored data to evaluate patient status; and
  - (k) electronically responding to the step of comparing to send to the patient a signal indicative of patient status or indicative that medical intervention has occurred.
2. The method of claim 1 wherein the signals from the patient are multiplexed and then converted into digital signals prior to transmission.
- 30 3. The method of claim 1 wherein the signals from the patient are conditioned prior to transmission.
4. The method of claim 1 wherein the signals are corrected for drift prior to transmission.
- 35 5. The method of claim 1 wherein drift as a result of patient respiration

is removed prior to transmission.

6. The method of claim 1 wherein the signals are rotated with respect to the trunk of the patient's body prior to transmission.

5

7. The method of claim 1 wherein the signals are shifted with respect to the patient's body prior to transmission.

8. The method of claim 1 wherein the number of electrodes connected to the patient is N, and N is a whole number integer, and the signals from the electrodes are reduced below N.

10 9. The method of claim 8 wherein the number N remains unaltered while the signals actually transmitted are changed dependent on the medical conditions of the patient.

15 10. The method of claim 9 wherein N is 12 and selected electrodes are switched off.

20 11. The method of claim 1 including the step of transmitting to the patient a signal controlling operation of equipment so that steps 1(c) through 1(f) are carried out under remote control.

25 12. The method of claim 11 wherein the step of remote control switches on or off at least one electrode.

30 13. The method of claim 1 wherein the step of receiving the transmitted signal compares the patient cardiac condition with EKG signals in a neural network and forms an indication of patient condition from operation of neural network.

14. The method of claim 13 including the preliminary step of inputting patient EKG signals.

35 15. The method of claim 1 wherein the steps of transmitting and receiving are carried out through a repeater located away from the patient.

16. The method of claim 15 including the step of transmitting the reduced data rate in a bandwidth fitting in a telephone line pass band.

5 17. The method of claim 1 wherein the patient is additionally monitored for blood oxygen content and a signal indicative of oxygen content is provided for transmission and is transmitted therewith.

10 18. The method of claim 17 including the step of monitoring oxygen level in four bands represented by digital data.

15 19. The method of claim 1 including the step of storing history of the patient and comparing the EKG obtained from that patient with the transmitted data in real time.

20 20. The method of claim 3 wherein said signal condition comprises correction for signal bias in a measured periodic signal by:  
(a) observing the measured periodic signal over a period of time significantly larger than the period of the periodic signal;  
(b) obtaining a moving average of the periodic signal from said observation; and  
(c) subtracting said moving average from said measured periodic signal thereby correcting said measured periodic signal for slowly varying bias changes.

25 21. The method of claim 4 wherein said signal drift correction comprises the steps of:  
(a) forming a digital filter which has a magnitude response which is flat in band pass and which posses sharp drop off on the flanks of said band pass; and  
(b) passing said signals through said digital filter thereby removing relatively low frequency drift from said signal prior to transmission of said signal.

30 35 22. The method of claim 6 wherein said signals are rotated with respect to the trunk of the patients body by:

- (a) defining a standard heart orientation;
- (b) defining a standard array for the placement of said electrodes onto the patient's body;
- (c) defining standard differences in signals from said electrodes from a heart in standard orientation;
- 5 (d) measuring differences in signals from a standard array of electrodes placed on said patient;
- (e) comparing said standard differences and said measured differences to determine an actual orientation of said patient's heart; and
- 10 (f) correcting said signals for non standard heart orientation based upon said comparison.

23. The method of claim 23 wherein said comparisons are made in a time domain.

15

24. A method of detecting cardiovascular difficulties with a patient having a history of such difficulties and the method comprises the steps of:

- (a) obtaining EKG data of the patient at the time of difficulties;
- (b) obtaining EKG data representing a set of cardiovascular difficulties indicated by EKG signals;
- 20 (c) transmitting EKG data from the patient from a remote location so that the patient EKG data is provided in real time along with movement of the patient;
- (d) processing the dynamic EKG data from the patient through a neural network dynamically with transmission of said EKG data representing a set of cardiovascular difficulties; and
- 25 (e) determining from said processing the presence of a cardiovascular condition and signaling the patient to seek medical assistance.

30

25. The method of claim 24 wherein the patient is provided with an alarm signal instructing the patient to attend a specific emergency medical facility.

35

26. The method of claim 24 including the step of transmitting the signal of the EKG of the patient from a remote location through a repeater system

interposed between the patient and a receiver for receiving the transmitted signal.

28. The method of claim 24 including the step of monitoring the patient  
5 continuously as part of a recovery program for the patient so that the patient may undertake normal patient activities remote from a medical facility.

29. The method of claim 28 including the step of transmitting to the patient an alarm signal indicating to the patient that medical treatment and intervention be undertaken by the patient prior to going to an emergency medical facility.  
10

30. The method of claim 24 including the step of directing the patient to an emergency medical facility and transmitting a signal to the emergency medical facility to indicate the patient is en route to the facility and also providing with that transmission an indication of the medical problem as indicated by the EKG of the patient.  
15

31. A system for monitoring the heart condition of patients during heart recovery enabling patient mobility, the system comprising:  
20

(a) a set of heart signal sensors connected with a transmitter to transmit from the patient signals indicative of heart conditions;

(b) a remote, central location receiver for receiving the heart patient signals transmitted therefrom, and wherein said receiver is connected to a heart signal output device;  
25

(c) a transmitter at the central location to enable transmission of medical personnel determined decisions based on the received patient signals; and

(d) a patient mounted receiver for receiving the transmitted instructions, wherein said receiver is connected to a patient mounted heart pacing system including electrodes for applying an electrical shock for heart operation.  
30

32. The system of claim 31 wherein said patient mounted pacing system includes electrodes for administering a sized shock to the patient heart.  
35

33. The system of claim 31 wherein said patient mounted receiver responds to transmitted instructions intended solely for that patient.

5 34. The system of claim 31 wherein said patient mounted receiver receives the transmitted instructions and displays alphanumeric instructions for the patient.

10 35. The system of claim 31 wherein said patient mounted receiver forms instructions as a result of the transmitted instructions wherein said patient mounted heart pacing system applies a specified heart pacing shock to the patient to regulate the heart beat for a specified interval at a specified rate.

15 36. The system of claim 31 wherein said patient mounted receiver varies the energy in the electrical shock from a heart pacing shock level to a defibrillation shock level.

20 37. The system of claim 31 wherein said patient mounted receiver applies first and second heart defibrillation shocks, and the second defibrillation shock is larger than the first.

25 38. The system of claim 31 wherein received signals are digitized and analyzed with a wavelet form of signal averaging leading to improved detection of late electrical potentials within a cardiac cycle.

30 39. The system of claim 31 wherein said patient mounted receiver signals to the patient a medication delivery signal, and said medication signal and said signal initiates delivery of a specified quantity of medicine.

35 40. The system of claim 31 wherein said patient mounted receiver receives the transmitted instructions and one of said instructions comprises a magnitude component for the electrical shock, and said signal is applied to a pulse circuit to control the signal for the patient mounted electrodes.

41. The system of claim 31 wherein said patient mounted receiver connects with a decoder which forms pulse selection signals for said heart pacing system.

5 42. The system of claim 31 wherein the said patient is implanted with a monitoring device which transmits electrical signals with or without accompanying pacemaker and/or defibrillator device.

10 43. A system for monitoring the heart condition of patients during heart recovery enabling patient mobility, the system comprising:

15 (a) a set of heart signal sensors connected with a patient mounted transmitter to transmit from the patient signals indicative of heart conditions;

15 (b) a remote, central location receiver for receiving the patient signals transmitted therefrom, and wherein said receiver is connected to a heart signal output device;

20 (c) a transmitter at the central location to enable transmission to the patient of determined instructions from medical personnel based on the received patient signals; and

20 (d) a patient mounted receiver for receiving the transmitted instructions, wherein said receiver is connected to a patient mounted heart pacing system including electrodes for applying an electrical shock for heart operation.

25 44. The system of claim 43 wherein said patient mounted pacing system includes electrodes for administering a sized shock to the patient heart.

30 45. The system of claim 43 wherein said patient mounted receiver responds to transmitted instructions intended solely for that patient.

46. The system of claim 43 wherein said patient mounted receiver receives the transmitted instructions and displays alphanumeric instructions for the patient.

35 47. The system of claim 43 wherein said patient mounted receiver forms instructions as a result of the transmitted instructions, wherein said

patient mounted heart pacing system applies a specified heart pacing shock to the patient to regulate the heart beat for a specified interval and at a specified rate.

5 48. The system of claim 43 wherein said patient mounted receiver varies the energy in the electrical shock from a heart pacing shock level to a defibrillation shock level.

10 49. The system of claim 43 wherein said patient mounted receiver applies first and second heart defibrillation shocks, and the second defibrillation shock is larger than the first.

50. The system of claim 1 further comprising:

- (a) a first display located at said central location;
- 15 (b) a second display located at said central location; and
- (c) a memory located at said central location, wherein said central location transmitter is operated by the medical personnel to form transmitted instructions for the patient based on
  - (i) patient medical data stored in said memory and
  - 20 displayed on said first display, and
  - (ii) heart conditions transmitted from the patient by means of said patient mounted receiver and displayed on said second display.

25 51. The system of claim 50 further comprising a medication delivery system which is affixed to the patient, wherein said patient mounted receiver signals to the patient a medication delivery signal, and said delivery medication delivery signal initiates delivery of a specified quantity of medicine from said medication delivery system.

30 52. The system of claim 50 wherein said patient mounted receiver receives the transmitted instructions, and one of said instructions comprises a magnitude component for the electrical shock, and said signal is applied to a pulse circuit to control the signal for the patient mounted electrodes.

35

53. The system of claim 50 wherein said stored patient medical data and

said transmitted heart conditions comprise EKG wave forms

54. The system of claim 50 wherein said patient mounted receiver connects with a decoder which forms pulse selection signals for said heart 5 pacing system.

55. The system of claim 50 wherein said central location transmitter transmits encoded signals for said patient mounted receiver, and transmits a second set of encoded signals to an emergency medical service.

10

56. The system of claim 55, wherein said central transmitter is operated by the medical personnel to form transmitted instructions for the patient based on patient medical data stored in a memory and the heart conditions transmitted from the patient by means of said patient mounted receiver.

15

57. The system of claim 56 wherein said patient medical data and said heart conditions are displayed simultaneously at said central location.

20 58. The system of claim 57 wherein said patient medical data is displayed on a first CRT and said second conditions are displayed on a second CRT.

59. The system of claim 56 wherein said patient medical data and said heart conditions comprise EKG wave forms.

25 60. The system of claim 57 wherein said heart conditions are displayed in real time as they are received from said patient mounted transmitter.

61. A method of monitoring and medically intervening in the health care of a recovering heart patient comprising the steps of:

30 (a) mounting heart monitoring sensors on a patient remote from a medical facility to thereby transmit the heart signals from the patient while mobile and away from the medical facility;

35 (b) receiving the patient transmitted signals from the patient at a central location and displaying aspects of the signals to enable medical analysis in real time;

(c) making discretionary medical diagnostic instructions for the

patient in the form of coded digital data transmissions transmitted from the central location to the patient;

5 (d) selectively receiving transmitted signals at the patient and forming from said signals remotely controlled pulses applied through a set of electrodes on the patient to alter operation of the heart; and

10 (e) transmitting digitilized patient EKG data to a physician carried receiver.

15 62. The method of claim 61 remotely controlled pulses comprise sized pulses.

10 63. The method of claim 61 wherein said patient received signals are intended solely for that patient.

15 64. The method of claim 61 wherein said patient received signals are displayed as alphanumeric instructions for the patient.

20 65. The method of claim 61 comprising the additional step of applying heart pacing shocks, as specified by said patient received signals, to the patient, wherein said heart pacing shocks are applied to the patient to regulate the heart beat for a specified interval and at a specified rate and as defined by said medical diagnostic instructions.

25 66. The method of claim 65 including the additional step of varying energy in said shocks from a heart pacing shock level to a defibrillation shock level.

30 67. The method of claim 66 wherein a first defibrillation shock and a second defibrillation shock are applied, and said second defibrillation shock is larger than said first defibrillation shock.

68. The method of claim 61 further comprising the additional steps of:

35 (a) providing a first display located at said central location;

(b) providing a second display located at said central location;

(c) providing a memory located at said central location;

(d) displaying patient medical data stored in said memory on said

first display;

(e) displaying heart conditions received as said patient received signals on said second display;

5 (f) forming said medical diagnostic instructions by comparing said first display and said second display; and

(g) transmitting said medical diagnostic instructions to the patient.

69. The method of claim 68 comprising the additional step of providing a medication system mounted on the patient, wherein said medical 10 diagnostic instructions signal said medication system to provide a specified amount of medication for the patient.

70. The method of claim 68 including the additional step of displaying said patient medical data and said heart conditions simultaneously at said 15 central location.

71. The method of claim 61 wherein said patient received signals comprise instructions, and one of said instructions comprises a magnitude component for said pulses, and said instructions cooperate with a pulse 20 circuit to control the power of electrical pulses supplied to said set of electrodes on the patient to alter operation of the heart.

72. The system of claim 68 wherein said stored patient medical data and said transmitted heart conditions comprise EKG wave forms.

25

73. The method of claim 61 including the additional steps of:

(a) processing said patient received signals with a decoder to form pulse selection signals;

30 (b) applying said pulse selection signals to a heart pacing system connected to said heart monitoring sensors; and

(c) controlling the beat rate of the patients heart based upon said patient received signals.

**AMENDED CLAIMS**

[received by the International Bureau on 17 August 1999 (17.08.99);  
original claims 1, 4, 8, 11, 31, 43 and 61 amended; new claims 27 and 74 - 89 added;  
remaining claims unchanged (15pages)]

1. A method of monitoring the cardiac status of a cardiac patient permitted to undertake normal activities comprising the steps of:

- (a) attaching a set of electrodes to a patient to enable normal activities;
- (b) forming a set of time dependent signals from the set of electrodes;
- (c) correcting the signals for systematic errors;
- (d) time multiplexing the signals;
- (e) converting the multiplexed signals into digital values having a data rate;
- (f) reducing the data rate while observing patient cardiac condition at the reduced data rate;
- (g) transmitting the reduced data rate of the patient cardiac status;
- (h) receiving at a central location the transmitted reduced data rate;
- (i) wherein the steps of transmitting and receiving are limited by the pass band of a connective link between the patient and the central location;
- (j) storing heart beat signal shape and condition data of the patient at the central location;
- (k) electronically comparing the received reduced data rate of the patient with the stored data to evaluate patient status; and
- (l) electronically responding to the step of comparing to send to the patient a signal indicative of patient status or indicative that medical intervention has occurred.

2. The method of claim 1 wherein the signals from the patient are multiplexed and then converted into digital signals prior to transmission.

3. The method of claim 1 wherein the signals from the patient are conditioned prior to transmission.

4. The method of claim 1 wherein the correction for systematic error comprises correcting the signals for drift prior to transmission.
5. The method of claim 1 wherein drift as a result of patient respiration is removed prior to transmission.
6. The method of claim 1 wherein the signals are rotated with respect to the trunk of the patient's body prior to transmission.
7. The method of claim 1 wherein the signals are shifted with respect to the patient's body prior to transmission.
8. The method of claim 1 wherein the number of electrodes connected to the patient is N, and N is a whole number integer, and the number of signals actually transmitted from the electrodes is N or less.
9. The method of claim 8 wherein the number N remains unaltered while the signals actually transmitted are changed dependent on the medical conditions of the patient.
10. The method of claim 9 wherein N is 12 and selected electrodes are switched off.
11. The method of claim 1 including the step of transmitting to the patient a signal controlling operation of equipment so that steps 1(d) through 1(g) are carried out under remote control.
12. The method of claim 11 wherein the step of remote control switches on or off at least one electrode.
13. The method of claim 1 wherein the step of receiving the transmitted signal compares the patient cardiac condition with EKG signals in a neural network and forms an indication of patient condition from operation of neural network.

14. The method of claim 13 including the preliminary step of inputting patient EKG signals.
15. The method of claim 1 wherein the steps of transmitting and receiving are carried out through a repeater located away from the patient.
16. The method of claim 15 including the step of transmitting the reduced data rate in a bandwidth fitting in a telephone line pass band.
17. The method of claim 1 wherein the patient is additionally monitored for blood oxygen content and a signal indicative of oxygen content is provided for transmission and is transmitted therewith.
18. The method of claim 17 including the step of monitoring oxygen level in four bands represented by digital data.
19. The method of claim 1 including the step of storing history of the patient and comparing the EKG obtained from that patient with the transmitted data in real time.
20. The method of claim 3 wherein said signal condition comprises correction for signal bias in a measured periodic signal by:
  - (a) observing the measured periodic signal over a period of time significantly larger than the period of the periodic signal;
  - (b) obtaining a moving average of the periodic signal from said observation; and
  - (c) subtracting said moving average from said measured periodic signal thereby correcting said measured periodic signal for slowly varying bias changes.
21. The method of claim 4 wherein said signal drift correction comprises the steps of:

(a) forming a digital filter which has a magnitude response which is flat in band pass and which posses sharp drop off on the flanks of said band pass; and

(b) passing said signals through said digital filter thereby removing relatively low frequency drift from said signal prior to transmission of said signal.

22. The method of claim 6 wherein said signals are rotated with respect to the trunk of the patients body by:

(a) defining a standard heart orientation;

(b) defining a standard array for the placement of said electrodes onto the patient's body;

(c) defining standard differences in signals from said electrodes from a heart in standard orientation;

(d) measuring differences in signals from a standard array of electrodes placed on said patient;

(e) comparing said standard differences and said measured differences to determine an actual orientation of said patient's heart; and

(f) correcting said signals for non standard heart orientation based upon said comparison.

23. The method of claim 23 wherein said comparisons are made in a time domain.

24. A method of detecting cardiovascular difficulties with a patient having a history of such difficulties and the method comprises the steps of:

(a) obtaining EKG data of the patient at the time of difficulties;

(b) obtaining EKG data representing a set of cardiovascular difficulties indicated by EKG signals;

(c) transmitting EKG data from the patient from a remote location so that the patient EKG data is provided in real time along with movement of the patient;

(d) processing the dynamic EKG data from the patient through a neural network dynamically with transmission of said EKG data representing a set of cardiovascular difficulties; and

(e) determining from said processing the presence of a cardiovascular condition and signaling the patient to seek medical assistance.

25. The method of claim 24 wherein the patient is provided with an alarm signal instructing the patient to attend a specific emergency medical facility.

26. The method of claim 24 including the step of transmitting the signal of the EKG of the patient from a remote location through a repeater system interposed between the patient and a receiver for receiving the transmitted signal.

27. The method of claim 26 including the step of positioning the repeater system away from the patient and away from the receiver.

28. The method of claim 24 including the step of monitoring the patient continuously as part of a recovery program for the patient so that the patient may undertake normal patient activities remote from a medical facility.

29. The method of claim 28 including the step of transmitting to the patient an alarm signal indicating to the patient that medical treatment and intervention be undertaken by the patient prior to going to an emergency medical facility.

30. The method of claim 24 including the step of directing the patient to an emergency medical facility and transmitting a signal to the emergency medical facility to indicate the patient is en route to the facility and also providing with that transmission an indication of the medical problem as indicated by the EKG of the patient.

31. A system for monitoring the heart condition of patients during heart recovery enabling patient mobility, the system comprising:

- (a) a set of heart signal sensors connected with a transmitter to transmit from the patient signals indicative of heart conditions
- (b) means for correcting said signals for systematic error prior to transmission;
- (c) a remote, central location receiver for receiving the heart patient signals transmitted therefrom, and wherein said receiver is connected to a heart signal output device;
- (d) a transmitter at the central location to enable transmission of medical personnel determined decisions based on the received patient signals; and
- (e) a patient mounted receiver for receiving the transmitted instructions, wherein said receiver is connected to a patient mounted heart pacing system including electrodes for applying an electrical shock for heart operation.

32. The system of claim 31 wherein said patient mounted pacing system includes electrodes for administering a sized shock to the patient heart.

33. The system of claim 31 wherein said patient mounted receiver responds to transmitted instructions intended solely for that patient.

34. The system of claim 31 wherein said patient mounted receiver receives the transmitted instructions and displays alphanumeric instructions for the patient.

35. The system of claim 31 wherein said patient mounted receiver forms instructions as a result of the transmitted instructions wherein said patient mounted heart pacing system applies a specified heart pacing shock to the patient to regulate the heart beat for a specified interval at a specified rate.

36. The system of claim 31 wherein said patient mounted receiver varies the energy in the electrical shock from a heart pacing shock level to a defibrillation shock level.

37. The system of claim 31 wherein said patient mounted receiver applies first and second heart defibrillation shocks, and the second defibrillation shock is larger than the first.

38. The system of claim 31 wherein received signals are digitized and analyzed with a wavelet form of signal averaging leading to improved detection of late electrical potentials within a cardiac cycle.

39. The system of claim 31 wherein said patient mounted receiver signals to the patient a medication delivery signal, and said medication signal and said signal initiates delivery of a specified quantity of medicine.

40. The system of claim 31 wherein said patient mounted receiver receives the transmitted instructions and one of said instructions comprises a magnitude component for the electrical shock, and said signal is applied to a pulse circuit to control the signal for the patient mounted electrodes.

41. The system of claim 31 wherein said patient mounted receiver connects with a decoder which forms pulse selection signals for said heart pacing system.

42. The system of claim 31 wherein the said patient is implanted with a monitoring device which transmits electrical signals with or without accompanying pacemaker and/or defibrillator device.

43. A system for monitoring the heart condition of patients during heart recovery enabling patient mobility, the system comprising:

(a) a set of heart signal sensors connected with a patient mounted transmitter to transmit from the patient signals indicative of heart conditions;

(b) means for correcting the signals for systematic error prior to transmission;

(c) a remote, central location receiver for receiving the patient signals transmitted therefrom, and wherein said receiver is connected to a heart signal output device;

(d) a transmitter at the central location to enable transmission to the patient of determined instructions from medical personnel based on the received patient signals; and

(e) a patient mounted receiver for receiving the transmitted instructions, wherein said receiver is connected to a patient mounted heart pacing system including electrodes for applying an electrical shock for heart operation.

44. The system of claim 43 wherein said patient mounted pacing system includes electrodes for administering a sized shock to the patient heart.

45. The system of claim 43 wherein said patient mounted receiver responds to transmitted instructions intended solely for that patient.

46. The system of claim 43 wherein said patient mounted receiver receives the transmitted instructions and displays alphanumeric instructions for the patient.

47. The system of claim 43 wherein said patient mounted receiver forms instructions as a result of the transmitted instructions, wherein said patient mounted heart pacing system applies a specified heart pacing shock to the patient to regulate the heart beat for a specified interval and at a specified rate.

48. The system of claim 43 wherein said patient mounted receiver varies the energy in the electrical shock from a heart pacing shock level to a defibrillation shock level.

49. The system of claim 43 wherein said patient mounted receiver applies first and second heart defibrillation shocks, and the second defibrillation shock is larger than the first.

50. The system of claim 1 further comprising:

- (a) a first display located at said central location;
- (b) a second display located at said central location; and
- (c) a memory located at said central location, wherein said central location transmitter is operated by the medical personnel to form transmitted instructions for the patient based on
  - (i) patient medical data stored in said memory and displayed on said first display, and
  - (ii) heart conditions transmitted from the patient by means of said patient mounted receiver and displayed on said second display.

51. The system of claim 50 further comprising a medication delivery system which is affixed to the patient, wherein said patient mounted receiver signals to the patient a medication delivery signal, and said delivery medication delivery signal initiates delivery of a specified quantity of medicine from said medication delivery system.

52. The system of claim 50 wherein said patient mounted receiver receives the transmitted instructions, and one of said instructions comprises a magnitude component for the electrical shock, and said signal is applied to a pulse circuit to control the signal for the patient mounted electrodes.

53. The system of claim 50 wherein said stored patient medical data and said transmitted heart conditions comprise EKG wave forms

54. The system of claim 50 wherein said patient mounted receiver connects with a decoder which forms pulse selection signals for said heart pacing system.

55. The system of claim 50 wherein said central location transmitter transmits encoded signals for said patient mounted receiver, and transmits a second set of encoded signals to an emergency medical service.

56. The system of claim 55, wherein said central transmitter is operated by the medical personnel to form transmitted instructions for the patient based on patient medical data stored in a memory and the heart conditions transmitted from the patient by means of said patient mounted receiver.

57. The system of claim 56 wherein said patient medical data and said heart conditions are displayed simultaneously at said central location.

58. The system of claim 57 wherein said patient medical data is displayed on a first CRT and said second conditions are displayed on a second CRT.

59. The system of claim 56 wherein said patient medical data and said heart conditions comprise EKG wave forms.

60. The system of claim 57 wherein said heart conditions are displayed in real time as they are received from said patient mounted transmitter.

61. A method of monitoring and medically intervening in the health care of a recovering heart patient comprising the steps of:

(a) mounting heart monitoring sensors on a patient remote from a medical facility to thereby transmit the heart signals from the patient while mobile and away from the medical facility;

(b) receiving the patient transmitted signals from the patient at a central location and displaying aspects of the signals to enable medical analysis in real time;

(c) making discretionary medical diagnostic instructions for the patient in the form of coded digital data transmissions transmitted from the central location to the patient;

(d) selectively receiving transmitted signals at the patient and forming from said signals remotely controlled pulses applied through a set of electrodes on the patient to alter operation of the heart; and

(e) transmitting digitized patient EKG data to a physician carried receiver.

62. The method of claim 61 remotely controlled pulses comprise sized pulses.

63. The method of claim 61 wherein said patient received signals are intended solely for that patient.

64. The method of claim 61 wherein said patient received signals are displayed as alphanumeric instructions for the patient.

65. The method of claim 61 comprising the additional step of applying heart pacing shocks, as specified by said patient received signals, to the patient, wherein said heart pacing shocks are applied to the patient to regulate the heart beat for a specified interval and at a specified rate and as defined by said medical diagnostic instructions.

66. The method of claim 65 including the additional step of varying energy in said shocks from a heart pacing shock level to a defibrillation shock level.

67. The method of claim 66 wherein a first defibrillation shock and a second defibrillation shock are applied, and said second defibrillation shock is larger than said first defibrillation shock.

68. The method of claim 61 further comprising the additional steps of:

- (a) providing a first display located at said central location;
- (b) providing a second display located at said central location;
- (c) providing a memory located at said central location;
- (d) displaying patient medical data stored in said memory on said first display;
- (e) displaying heart conditions received as said patient received signals on said second display;

(f) forming said medical diagnostic instructions by comparing said first display and said second display; and

(g) transmitting said medical diagnostic instructions to the patient.

69. The method of claim 68 comprising the additional step of providing a medication system mounted on the patient, wherein said medical diagnostic instructions signal said medication system to provide a specified amount of medication for the patient.

70. The method of claim 68 including the additional step of displaying said patient medical data and said heart conditions simultaneously at said central location.

71. The method of claim 61 wherein said patient received signals comprise instructions, and one of said instructions comprises a magnitude component for said pulses, and said instructions cooperate with a pulse circuit to control the power of electrical pulses supplied to said set of electrodes on the patient to alter operation of the heart.

72. The system of claim 68 wherein said stored patient medical data and said transmitted heart conditions comprise EKG wave forms.

73. The method of claim 61 including the additional steps of:

(a) processing said patient received signals with a decoder to form pulse selection signals;

(b) applying said pulse selection signals to a heart pacing system connected to said heart monitoring sensors; and

(c) controlling the beat rate of the patients heart based upon said patient received signals.

74. A method of monitoring the coronary status of a patient permitted to undertake normal activities after a coronary episode comprising the steps of:

- (a) attaching a set of electrodes to a patient after the coronary episode to enable the patient to undertake normal activities of life after the episode;
- (b) forming time dependent signals from the set of electrodes;
- (c) time multiplexing the signals;
- (d) digitizing the multiplexed signals at a selected data rate;
- (e) reducing the data rate while preserving patient coronary condition in the reduced data rate;
- (f) transmitting the reduced data rate patient coronary condition;
- (g) receiving at a central location the transmitted reduced data rate patient coronary condition;
- (h) wherein
  - (i) the steps of transmitting and receiving are limited by the pass band of a connective link between the patient and the central location
  - (ii) the number of electrodes connected to the patient is  $N$ , and  $N$  is a whole number integer, and
  - (iii) the number  $N$  remains unaltered while the signals actually transmitted are  $N$  or less and changed dependent on the medical conditions of the patient;
  - (i) evaluating the received reduced data rate patient coronary condition to dynamically make a determination of patient coronary condition departing from patient related coronary heart beat signal shape; and
  - (j) electronically responding to the step of evaluating to send to the patient a signal indicative of patient coronary conditions or indicative that medical intervention has been initiated.

75. The method of claim 74 wherein  $N$  is 12 and selected electrodes are switched off.

76. The method of claim 74 including the step of transmitting to the patient a signal controlling operation of equipment so that steps 30(c) through 30(f) are carried out under remote control.

77. The method of claim 76 wherein the step of remote control switches on or off at least one electrode.

78. The method of claim 74 wherein the step of receiving the transmitted signal compares the patient coronary condition with EKG signals in a neural network and forms an indication of patient condition from operation of neural network.

79. The method of claim 78 including the preliminary step of inputting patient EKG signals into a central location memory.

80. The method of claim 74 including the step of transmitting the reduced data rate in a bandwidth fitting in a telephone line pass band.

81. The method of claim 74 wherein the signals are corrected for drift prior to transmission.

82. The method of claim 74 wherein drift as a result of patient respiration is removed prior to transmission.

83. The method of claim 74 wherein the signals are rotated with respect to the trunk of the patient's body prior to transmission.

84. The method of claim 74 wherein the signals are shifted with respect to the patient's body prior to transmission.

85. The method of claim 74 wherein the patient is additionally monitored for blood oxygen content and a signal indicative of oxygen content is provided for transmission and is transmitted in four bands represented by digital data.

86. The method of claim 74 including the step of storing history of the patient and comparing the EKG obtained from that patient with the transmitted data in real time.

87. The method of claim 74 wherein the signals from the patient are conditioned prior to transmission, wherein said signal condition comprises correction for signal bias in a measured periodic signal by:

- (a) observing the measured periodic signal over a period of time significantly larger than the period of the periodic signal;
- (b) obtaining a moving average of the periodic signal from said observation; and
- (c) subtracting said moving average from said measured periodic signal thereby correcting said measured periodic signal for slowly varying bias changes.

88. The method of claim 81 wherein said signal drift correction comprises the steps of:

- (a) forming a digital filter which has a magnitude response which is flat in band pass and which posses sharp drop off on the flanks of said band pass; and
- (b) passing said signals through said digital filter thereby removing relatively low frequency drift from said signal prior to transmission of said signal.

89. The method of claim 83 wherein said signals are rotated with respect to the trunk of the patients body by:

- (a) defining a standard heart orientation;
- (b) defining a standard array for the placement of said electrodes onto the patient's body;
- (c) defining standard differences in signals from said electrodes from a heart in standard orientation;
- (d) measuring differences in signals from a standard array of electrodes placed on said patient;
- (e) comparing said standard differences and said measured differences to determine an actual orientation of said patient's heart; and
- (f) correcting said signals for non standard heart orientation based upon said comparison.

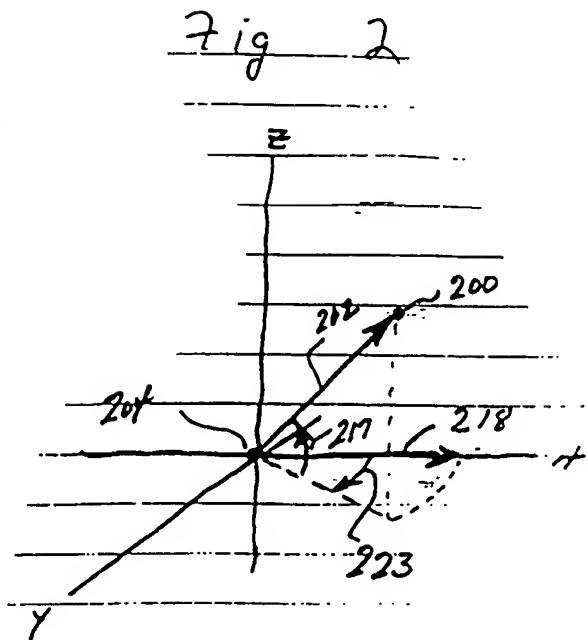
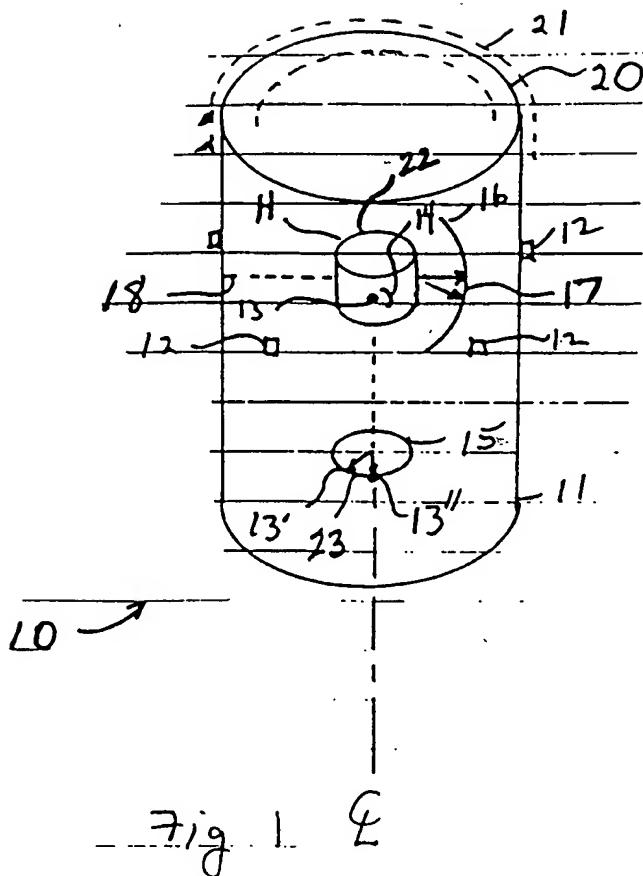
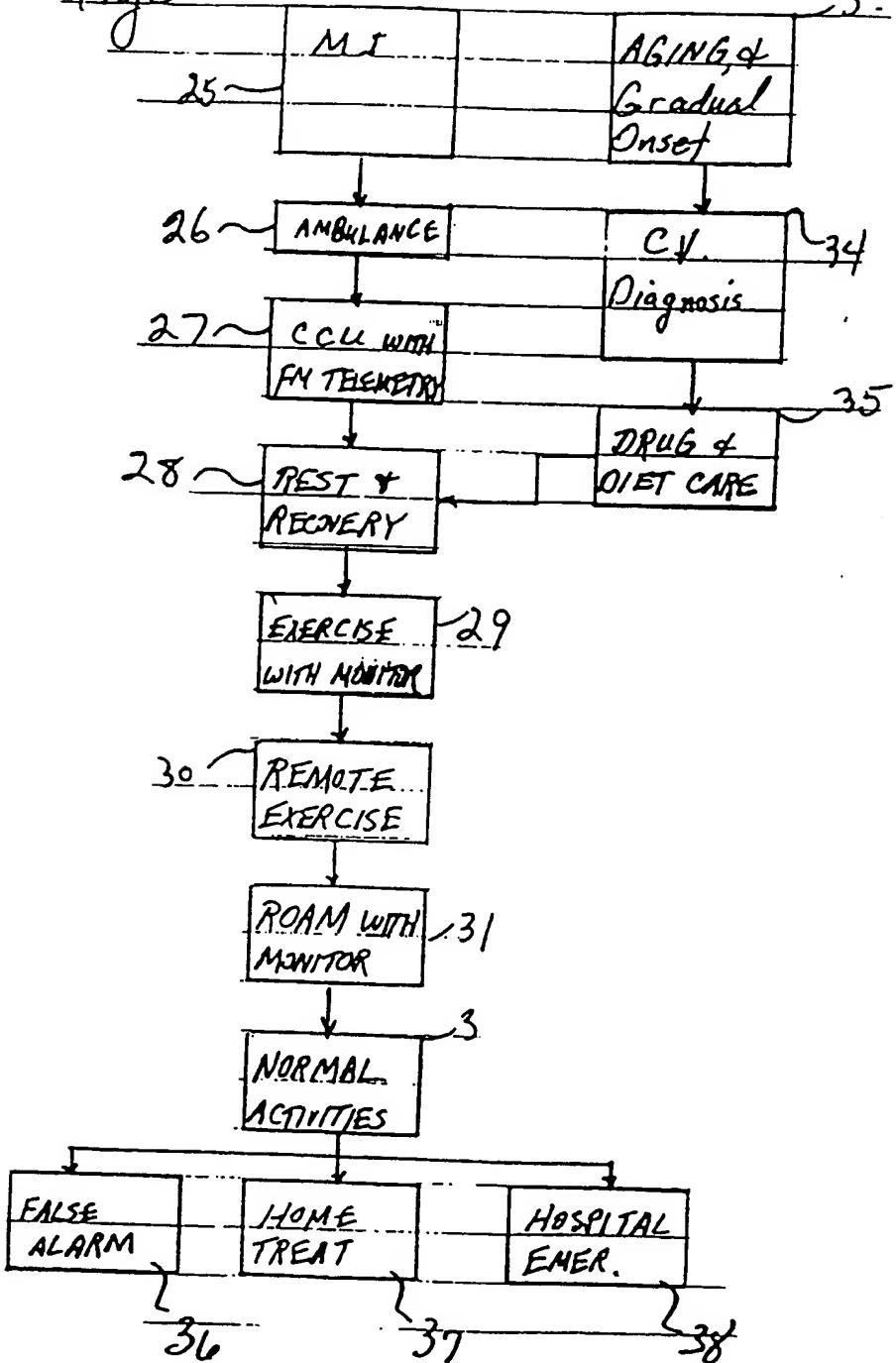
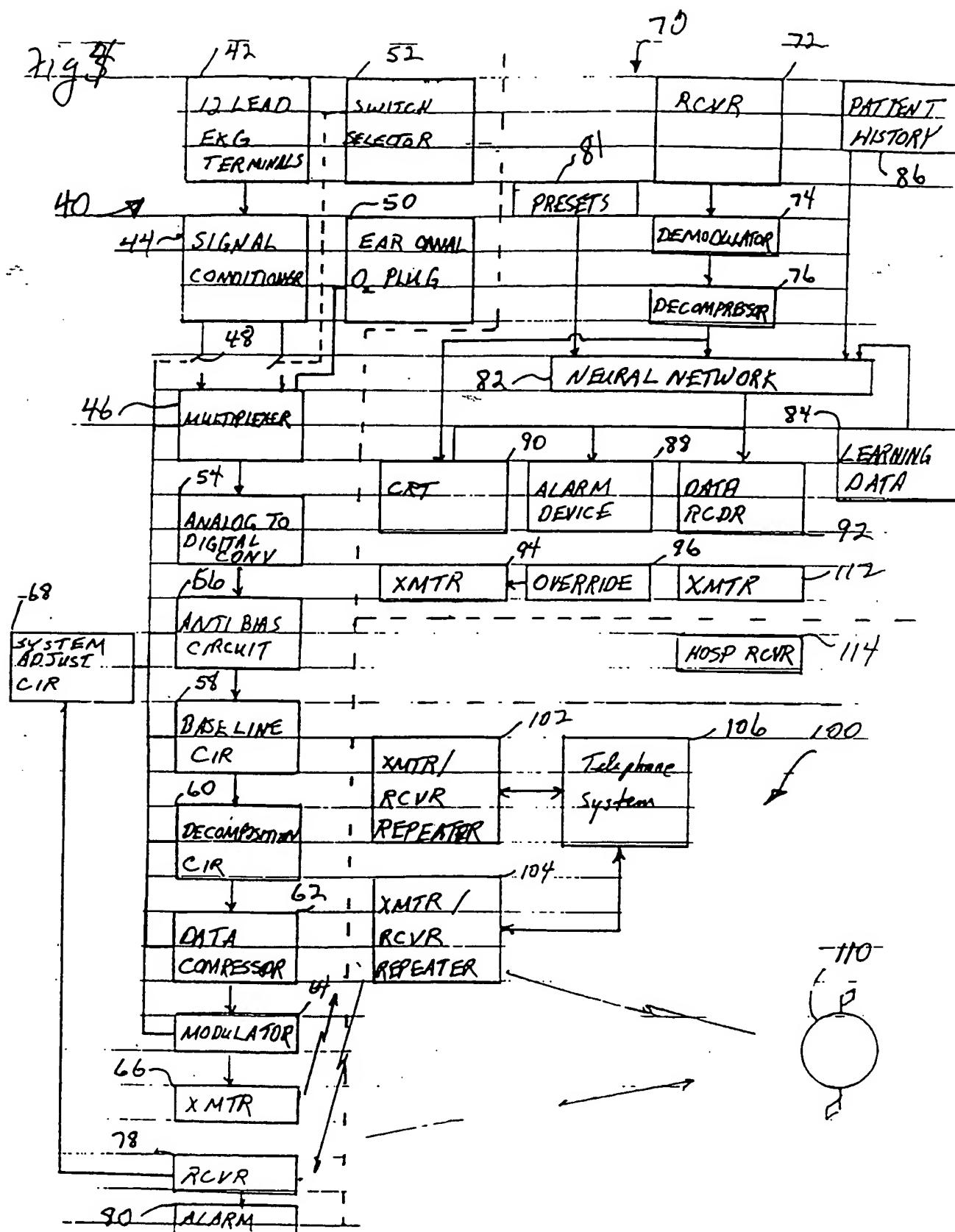
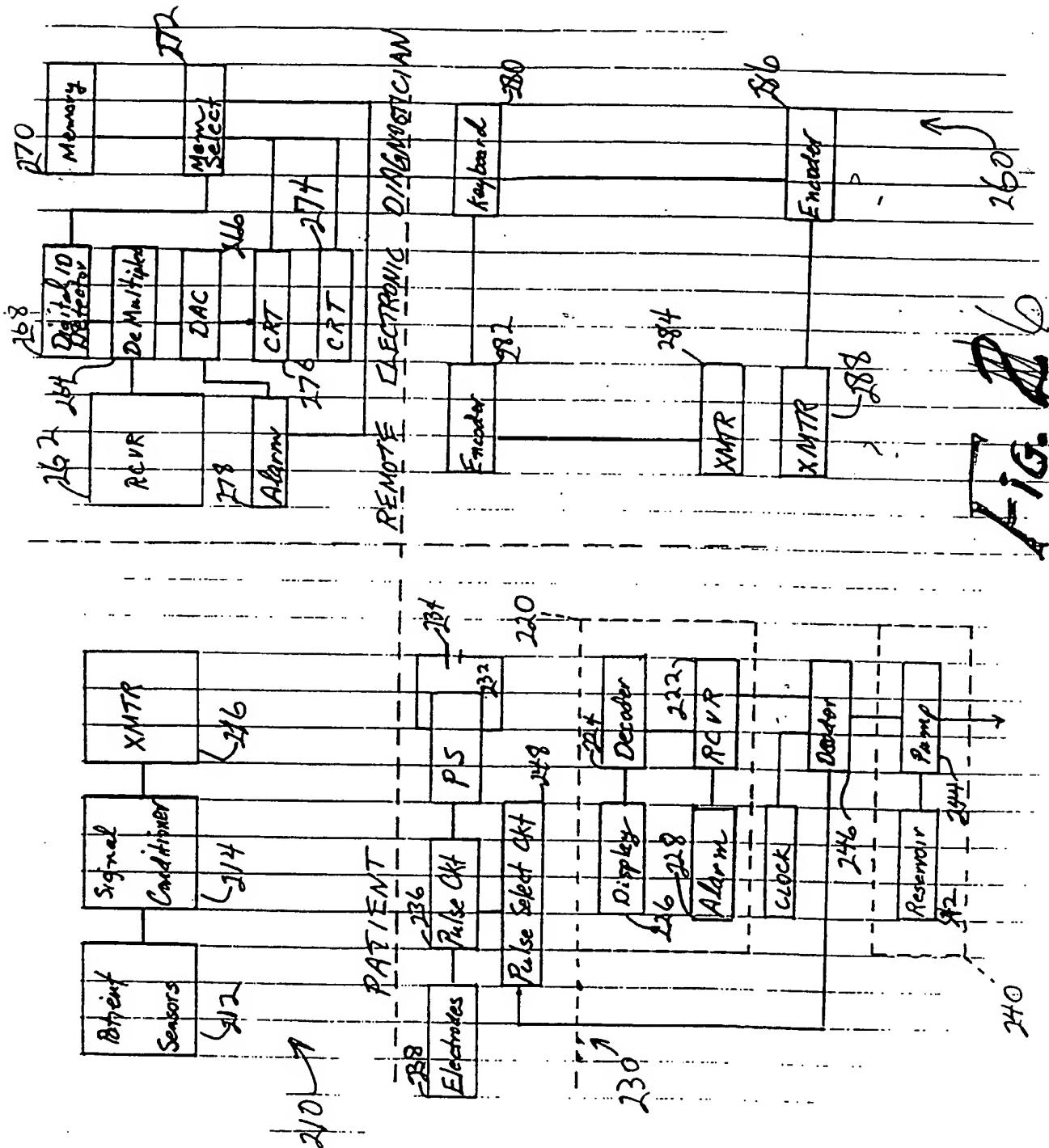


Fig. 3







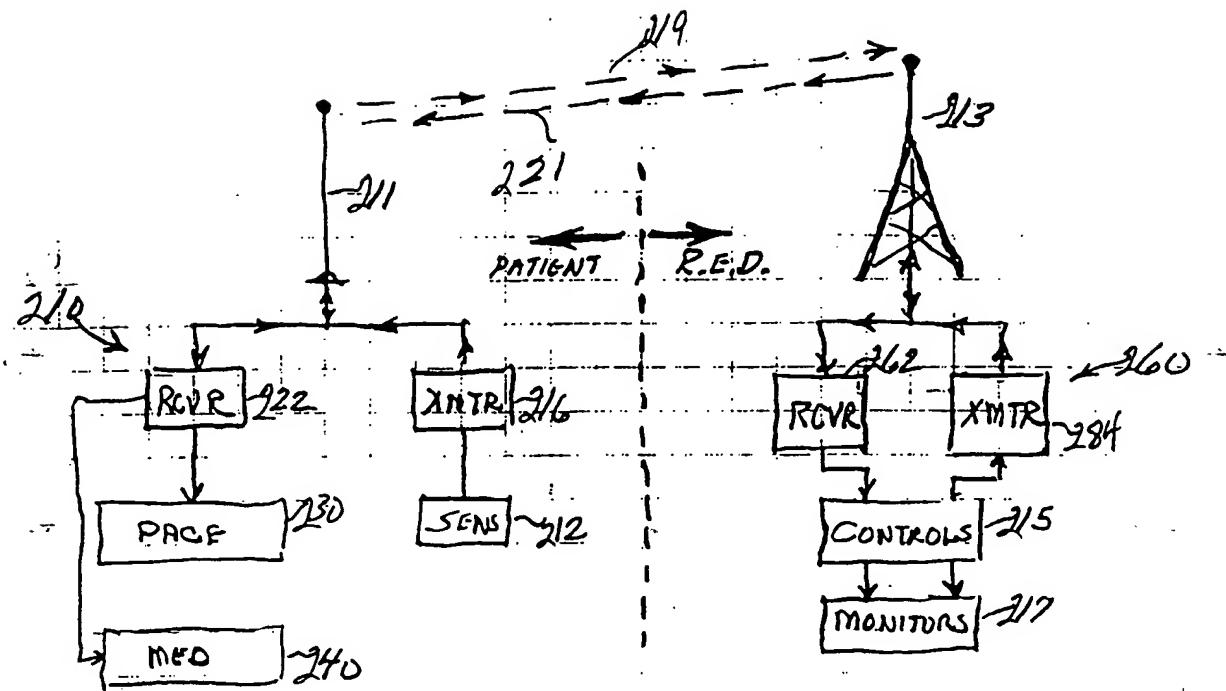


FIG. 5

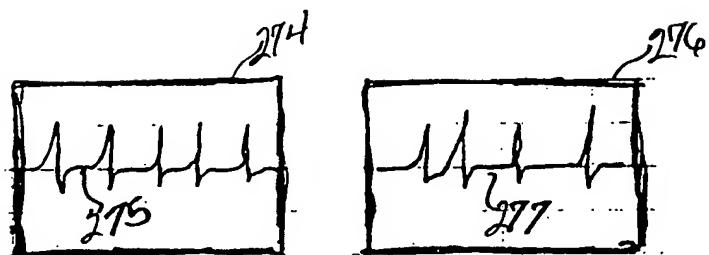


FIG. 37

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/02550

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/0402, 0404, 0452

US CL :128/903, 904; 600/509, 515, 522

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128903, 904; 600/509, 515, 522

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, WEST 1.0

Search Terms: EKG, time division multiplexing, neural network, remote location, alarm

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,724,455 A (UNGER) 03 April 1973, Fig. 1 (defibrillator), col. 4 lines 13-54, and col. 5 lines 53-60.	31-33, 36, 43-45, 48
---		-----
Y		1
Y,P	US 5,832,490 A (RILEY) 03 November 1998, Fig.1; col. 3 lines 40-44, and 65 to bottom; and col. 4 lines 1-5.	1-3, 17
A	US 5,694,940 A (UNGER et al) 09 December 1997, entire document.	1

Further documents are listed in the continuation of Box C.

See patent family annex.

Special categories of cited documents:	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A*	document defining the general state of the art which is not considered to be of particular relevance	-----
*E*	earlier document published on or after the international filing date	*X*
*L*	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y*
*O*	document referring to an oral disclosure, use, exhibition or other means	*A*
*P*	document published prior to the international filing date but later than the priority date claimed	document member of the same patent family

Date of the actual completion of the international search

31 MARCH 1999

Date of mailing of the international search report

19 APR 1999

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer  
CARL H. LAYNO

Telephone No. (703) 308-3694

**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/US99/02550

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 27 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  

The claim does not exist.
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER: \_\_\_\_\_**

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**